Response of RJ Lee Group

to the
United States Environmental Protection Agency Region IX
Response (dated April 20, 2006) to the November 2005
National Stone, Sand & Gravel Association Report
Prepared by the R.J. Lee Group, Inc [sic]
"Evaluation of EPA's Analytical Data from the
El Dorado Hills Asbestos Evaluation Project"

Regarding
Evaluation of EPA's Analytical Data from the El Dorado Hills Asbestos Evaluation Project

Exhibit A

Date: July 2006

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Preface

In October 2004, the U.S. Environmental Protection Agency (EPA) Region 9 conducted a series of tests in and around El Dorado Hills (EDH), California, to assess the potential exposure of residents to naturally occurring asbestos (NOA). EPA released a report of its results to the general public in May 2005 [El Dorado Hills Naturally Occurring Asbestos Multimedia Exposure Assessment El Dorado Hills, California: Preliminary Assessment and Site Inspection Report – Interim Final]. At the request of the National Stone, Sand & Gravel Association (NSSGA), RJ Lee Group, Inc. (RJLG) conducted a review of EPA's May 2005 report and underlying data and issued a report (dated November 2005) entitled "Evaluation of EPA's Analytical Data from the El Dorado Hills Asbestos Evaluation Project". EPA Region 9 issued a letter (Meer) dated March 9, 2006 to RJLG and NSSGA requesting the submission of supporting documentation to RJLG's November 2005 report. On April 20, 2006, EPA Region 9 issued a report entitled "Response to the November 2005 National Stone, Sand & Gravel Association Report Prepared by the R.J. Lee Group Inc [sic] 'Evaluation of EPA's Analytical Data from the El Dorado Hills Asbestos Evaluation Project'" (Region 9 April 20 Response). In addition to the sequence of reports listed above, Mr. Gregory Meeker, USGS and a consultant to the EPA, in an undated letter, prepared a "Response to Questions Submitted by Dr. Vicki Barber, Superintendent of Schools, El Dorado County, California regarding Asbestiform Amphiboles" (Meeker Response). Dr. Barber's questions were submitted to Dr. Robert Virta, USGS, in an email dated February 1, 2006.

The following is RJLG's response to the EPA Region 9 April 20, 2006 Report entitled "Response to the November 2005 National Stone, Sand & Gravel Association Report Prepared by the R.J. Lee Group Inc [sic] 'Evaluation of EPA's Analytical Data from the El Dorado Hills Asbestos Evaluation Project'". Upon review of the Region 9 April 20 response; RJLG concluded there are a number of important differences of opinion as well as factual misstatements in the Response that RJLG must address to ensure an accurate public record. To avoid unnecessary reiteration and to ensure that EPA's statements are kept in context, RJLG's responses are provided in the form of annotated comments within the EPA Region 9 April 20 Response. RJLG has italicized the text of Region 9 Response; sections of the Response that warrant correction or response are shown in bold italics, and are followed by the RJLG Response.

1.0 EPA Opening Paragraph

"This document constitutes the United States Environmental Protection Agency Region 9 (EPA Region 9) response to the major findings and conclusions of the National Stone, Sand & Gravel Association report "Evaluation of EPA's Analytical Data from the El Dorado Hills Asbestos Evaluation Project" prepared by the R. J. Lee Group (R. J. Lee Report). A more detailed analysis will be completed after additional information is received from the R. J. Lee Group and the National Stone, Sand & Gravel Association,[1] and the United States Geological Survey (USGS)."

"The R. J. Lee Report draws conclusions that are contradicted by the El Dorado Hills data and by generally accepted scientific principles for measuring asbestos exposure."

Overview

"The R. J. Lee Group review of the EPA data was contracted by the National Stone, Sand & Gravel Association. The El Dorado County Office of Education funded the three reviewers who wrote letters in support of the R. J. Lee Report and whose reviews are included in this response."

"The EPA Region 9 El Dorado Hills Naturally Occurring Asbestos Exposure Assessment was designed to measure the exposures to asbestos fibers, if any, that resulted from sports and play activities that disturbed dust and soil. ***EPA Region 9 adhered to accepted EPA standards for sampling and analysis, including rigorous quality assurance/quality control, and to the standard methodologies of EPA exposure and risk assessment."***

RJLG Response: These "accepted EPA standards" were developed in the context of occupational exposures to commercially processed asbestos. Naturally occurring asbestos (NOA) exposures are qualitatively different in nature and extent and any valid policy for addressing

[1] **[EPA footnote]** On March 9, 2006, EPA Region 9 sent a letter (Meer) to the RJ Lee Group and the National Stone, Sand, & Gravel Association asking for additional information to support the findings and conclusions of the R.J. Lee Report.

them must recognize the relevant differences and account for them in the scientific methodology used to identify and estimate exposures and related health risks. RJLG's analyses responsibly address the implications of NOA's unique characteristics for scientifically assessing exposure and risks; EPA's do not.

"The R. J. Lee Report Criticizes EPA Region 9 for Using Established Scientific and Public Health Protocols -*In assessing naturally occurring asbestos exposures in El Dorado Hills, EPA evaluated asbestos exposures using the PCME (phase contrast microscopy equivalent) asbestos fiber size classification.* ***The PCME classification was used because human epidemiological studies, which form the basis of knowledge of asbestos health effects, measured asbestos fiber concentrations using phase contrast microscopy (PCM) analytical methods."***

RJLG Response: It is important to note that the human epidemiological studies that assessed the dose of asbestos exposure did indeed use the PCM concentration (or midget impinger concentrations converted to PCM) as the index of exposure. It is just as important to note that these epidemiological studies involved cohorts that were exposed to fairly pure commercial asbestos and not mixed dusts. The PCM concentration in commercial asbestos environments would fairly reliably indicate the typical asbestos exposure, while in mixed dust environments like that of the Quebec chrysotile miner studies, it would not. In fact, mixed dust environment epidemiological studies were explicitly excluded from the IRIS assessments of how much exposure contributes to disease. The measured dose in Quebec miners and millers included significant antigorite cleavage fragments in addition to chrysotile and did not correspond to a similar disease outcome as the other epidemiology studies. Using PCMe in a mixed dust environment does not equate to use of PCM in a commercial asbestos environment. Attachment A-1 illustrates the differences in particle types between minerals used in the IRIS Study (i.e., chrysotile textile and insulation products), particles from mixed mineral environments excluded from the IRIS study (i.e., chrysotile mining), and with El Dorado soil samples. The fibers from environments included in IRIS show no evidence of mineral fragments with aspect ratios in excess of 5:1, while the particles excluded from IRIS have a substantial presence of asbestos fibers (with mineral fragments). In the El Dorado soil samples, note the absence of any visible fibers.

"PCME is the standard term for fibers counted by more modern analytical methods that are of equivalent size to those fibers that would be seen by PCM analysis, and includes fibers with a length to width aspect ratio of 3 to 1 or greater."

RJLG Response: PCMe was applied to supplement the basic counting dimensions (>5 um long; ≥3:1 aspect ratio) used in PCM with mineral identification

through proportional elemental analysis and crystal structure that the electron microscope methods can provide. The PCMe method allows for discriminating between different mineral habits of the same mineral. Just because a particle fits the counting criteria of the PCM analysis and it is one of the minerals that can form asbestos, does not mean that the particle is asbestos. Asbestos is formed under special geological and mineralogical conditions in nature. It is not formed by mechanically breaking prismatic rock fragments into PCMe countable particles. PCMe was developed to sort out nonasbestos particles, including nonasbestos amphiboles, from asbestos. The procedure for the determination of the PCMe is included in the NIOSH 7400/7402 methods. NIOSH 7402 recognizes that nonasbestos amphiboles are a potential interference[2] for the method. In a mixed dust environment, PCMe is not used to determine the fiber concentration, rather, it is used to determine the percentage of fibers that are asbestos. OSHA's method ID-191[3] specifically describes the characteristics of asbestos and nonasbestos amphiboles. Crane[3] provides additional guidance on how to minimize the interference in the analysis. IRIS[4] is based on and specifically addresses the measurement of regulated asbestos. Crane,[5] RJLG,[6] and RTI[7] reported the same result of no asbestos present when analyzing crayon samples which Lab/Cor claimed contained tremolite asbestos on the basis of tremolite particles with a ≥3:1 aspect ratio (Seattle Post Intelligencer[8]).

"EPA considered PCME fibers in our analysis of the El Dorado data to be consistent with the existing health databases and risk assessment procedures used by EPA, California EPA (Cal/EPA), the World Health Organization, and other federal agencies and international organizations."

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[2] **[RJLG footnote]** NIOSH 7402 (1994). "Asbestos by TEM", issue 2, August 15, 1994. "There are, however, several minerals (e.g., pyroxenes, massive amphiboles, and talc fibers) which are chemically similar to asbestos and can be considered interferences", page 7.

[3] **[RJLG footnote]** D. T. Crane (1992). "Polarized Light Microscopy of Asbestos," OSHA Analytical Methods Manual, Method ID-191.

[4] **[RJLG footnote]**] US Environmental Protection Agency, Integrated Risk Information System (IRIS), http://www.epa.gov/iris/subst/0371.htm.

[5] **[RJLG footnote]** Daniel T. Crane; US Department of Labor, Occupational Safety & Health Administration (OSHA): "Report of Analysis of Crayons for the Presence of Asbestos", June 12, 2000.

[6] **[RJLG footnote]** RJ Lee Group (2000). Analytical Report, LSH005429, October 19, 2000.

[7] **[RJLG footnote]** Beard, M.E., Crankshaw, O.S., Ennis, J.T., and Moore, C.E., "Analysis of Crayons for Asbestos and other Fibrous Materials, and Recommendations for Improved Analytical Definitions", Research Triangle Institute Center for Environmental Measurements and Quality Assurance, Earth and Mineral Sciences Department, February 28, 2001.

[8] **[RJLG footnote]** Seattle Post Intelligencer, May 30, 2000.

RJLG Response: Risk models are based upon exposures to commercially produced asbestos. The concept of a PCMe fiber is based upon an assumed exposure to commercial asbestos fibers. The PCMe fibers in the El Dorado Hills data are not dimensionally consistent with the fibers in the airborne dust exposures that underlie health databases and risk assessment procedures. Existing health databases and risk assessment procedures, both in the U.S. and internationally, are based on the assessment of the concentration of naturally formed asbestiform fibers; they do not include all serpentine or amphibole fragments with a ≥3:1 aspect ratio. Localized clusters of mesothelioma, found in areas not associated with commercial asbestos, have consistently been linked to an exposure to minerals that formed as asbestos fibers. The EU considers asbestos and nonasbestos amphiboles and serpentines to be different and has conducted a major study[9] to characterize the differences between asbestos and nonasbestos mineral particle populations specifically for the purpose of developing procedures to discriminate between the two. The EU published a method[10] combining polarized light microscopy (PLM) and PCM for discriminating between asbestos and nonasbestos amphiboles. The EU has a zero tolerance for asbestos in imported products but no limit on nonasbestos amphiboles or serpentines. In California, the Carb 435 method[11] for assessing the asbestos content of serpentine ores specifically discriminates between nonasbestos serpentine and asbestos (chrysotile).

"This approach was rejected by the R.J. Lee Group, which instead advocates use of asbestos fiber definitions which are not health based or supported by the majority of experts in the health community, and which would not allow comparison to the existing epidemiologic data on asbestos related cancers."

RJLG Response: The definition of asbestos used by RJLG is the same as the definition used by other experts[3,12,13] and is the definition that forms the basis of our understanding of the health effects of asbestos.

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[9] **[RJLG footnote]** Burdett, G., "Final report for R42:70: Quantitative measurement of asbestos and other fibres in bulk materials IR/L/MF/98/02", Environmental Measurement Group, Health and Safety Laboratory, An agency of the Health and Safety Executive, Broad Lane, Sheffield, S3 7HQ, August 1998.

[10] **[RJLG footnote]** Schneider, T., Davies, L., Burdett, G., Tempelman, J., Puledda, S., Jorgensen, O., Buchanan, D., and Paoletti, L., "Development of a method for the determination of low contents of fibres in bulk material ", Analyst, June 1998, Vol. 123 (1393-1400).

[11] **[RJLG footnote]** California Air Resources Board (1991). "Determination of Asbestos Content of Serpentine Aggregate".

[12] **[RJLG footnote]** William J. Campbell, Eric B. Steel, Robert L. Virta and Michael H. Eisner. "Relationship of Mineral Habit to Size Characteristics for Tremolite Cleavage Fragments and Fibers," U.S. Dept. of the Interior, Bureau of Mines, 1979, RI 8367.

EPA's Quality Assurance Project Plan (QAPP) for the El Dorado Hills Study did not define asbestos on the basis of Region 9's proposed PCMe fiber concentration; rather, it was based on the geological/mineralogical definition.[14] The geological definition of asbestos was the basis for the identification of asbestos in El Dorado County and the resulting public concerns. The dimensional characteristics of asbestiform minerals that give them their unique mechanical properties are also recognized as the critical factors affecting the potency of airborne particles.[15,16,17] Using the PCMe counting criteria as the definition of asbestos will decrease the reliability of the measurement of the most toxic component of an exposure in a mixed mineral dust.

"The R. J. Lee Report Claims that EPA Region 9 Misapplied Fiber Counting Protocols - *The R. J. Lee Report claims that EPA Region 9 inflated the fiber counts in the El Dorado Hills air data by misapplying the International Standards Organization (ISO) method 10312 (the analytical method used by EPA to analyze the El Dorado air samples) and including PCME structures with a 3 to 1 length to width aspect ratio in our analysis.* ***The R. J. Lee Report maintains that EPA should only have counted structures which met the general 5 to 1 aspect ratio fiber size definition described in the body of the ISO 10312 method. However, Annex C and Annex E of the ISO 10312 method specifically authorize the counting of PCME structures with a 3 to 1 aspect ratio."***

RJLG Response: The ISO 10312 method does not recommend any specific deviations from the method as written; the method recognizes that for the purpose of risk assessment, counting of specific subsets of the asbestos population is acceptable within the method. The method provides a general procedure within which such measurements are made and reported. The ISO 10312 method also specifically states that

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[13] **[RJLG footnote]** G. Burdette and O. Jorgensen (1998). "Annexes to final report for R42:70: Quantitative measurement of asbestos and other fibres in bulk materials (Part 2)", UK H&SE.

[14] **[RJLG footnote]** Ecology and Environment, Inc. (2004). El Dorado Hills Naturally Occurring Asbestos Multimedia Exposure Assessment El Dorado Hills, California Quality Assurance Project Plan Working Draft, September 2004. Page ix: "asbestos: Asbestos is the generic name used for a group of naturally occurring mineral silicate fibers of the serpentine and amphibole series. Asbestos is composed of fiber bundles that are made up of extremely long and thin fibers that are easily separated from one another".

[15] **[RJLG footnote]** EPA (2000). Sampling and Quality Assurance Plan for Libby, Montana Environmental Monitoring for Asbestos Baseline Monitoring for Source Area and Residential Exposure to Tremolite-Actinolite Asbestos Fibers, January 4, 2000, page 7.

[16] **[RJLG footnote]** D. W. Berman and K. Crump (2003). Technical support document for a protocol to assess asbestos-related risk," EPA, U.S. Environmental Protection Agency, Revision of original from September 4, 2001, Peer-reviewed consultation held in San Francisco on February 25-26, 2003.

[17] **[RJLG footnote]** ATSDR (2002). Expert Panel on Health Effects of Asbestos and Synthetic Vitreous Fibers (SVF): The Influence of Fiber Length; Premeeting Comments", ATSDR Agency for Toxic Substances and Disease Registry, October 29-30, 2002.

the use of the method as written will not discriminate between asbestos particles and nonasbestos amphibole particles. The ISO 10312 method would have permitted the counting of only fibers >10 µm and <0.4 µm for the purpose of risk analysis which would have focused on the fibers that present asbestos-like risk.[16]

The ISO 10312 method adopted counting particles with a 5:1 aspect ratio specifically to minimize the counting of amphibole and other mineral fragments which are not asbestos. The consensus of the international scientific community was that asbestos fibers are rarely, if ever, found as particles with a <3:1 aspect ratio and therefore, counting such particles represented a waste of analytical resources and diluted the measurement of particles that have potential health significance. The change in aspect ratio from ≥3:1 to ≥5:1 did not affect the accuracy of identification or the count of asbestos fibers.

Moreover EPA did not follow the ISO 10312 rules with any consistency as illustrated by the Lab/Cor particle images shown in Attachment A-3. Most of the particles photographed by Lab/Cor do not meet the ISO 10312 requirement of "substantially parallel or stepped sides."

"Another example of misleading information is the R.J. Lee Report's statistical evaluation and resulting conclusions regarding the concentrations of asbestos structures detected in the EPA air samples. All of the established EPA, National Institute of Occupational Safety and Health (NIOSH), and ISO analytical methods require the counting of asbestos bundles, recognizing the significance of bundles to proper characterization of asbestos fiber levels. ***The R.J. Lee Report did not include asbestos bundles in its analysis of the data, thereby undercounting the number of structures."***

RJLG Response: All bundles identified by Lab/Cor were included in RJLG's computation of fiber concentrations and the statistical analysis of the concentration data. Bundles were excluded from the analysis of the size distribution because it was unclear what dimension Lab/Cor was reporting (i.e., the overall width of the bundle or the width of individual fibrils that comprise the bundle). No photographs were provided to illustrate the characteristics of the particles Lab/Cor was identifying as bundles. As noted by Mr. John Addison,[18] there are questions concerning the identification of bundles in these samples.

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[18] **[RJLG footnote]** J. Addison (2006). "Comments on the Report Dated November 2005, by the RJ Lee Group of the 'Evaluation of EPA's Analytical Data from the El Dorado Hills Asbestos Evaluation Project' as presented by the EPA in the document 'El Dorado Hills, Naturally Occurring Asbestos Multimedia Exposure Assessment Preliminary Assessment and Site Inspection Report Interim Final", March 23, 2006.

"The R. J. Lee Report Claims that EPA Region 9 Misidentified Amphibole Minerals -The R. J. Lee Report concludes that EPA misidentified actinolite asbestos fibers in the El Dorado soil samples by using inappropriate extinction angle criteria. The R. J. Lee Group conclusion is contradicted by the National Institute of Standards and Technology (NIST) and the major analytical methods used for analysis of asbestos in soil and bulk samples."

RJLG Response: One hundred eighty-five (185) soil samples were analyzed using polarized light microscopy by Asbestos TEM Laboratory, Inc. Each sample had reported extinction angles of twelve (12) degrees, an index of refraction of 1.672 (parallel) and 1.652 (perpendicular), and described the amphiboles particles as "Needles." No evidence of particles with asbestiform habit, (splayed ends, curvature, flexibility, bundles, or high aspect ratio) was noted in any sample. RJLG's independent analysis found no asbestiform particles in the El Dorado Hills soils tested.

The NIST reference standard (SRM 1867a), certified by NIST as having a mixed asbestos/nonasbestos population, contains asbestiform particles with parallel extinction and nonasbestos cleavage fragments with oblique extinction. If one does not examine the particles with respect to other asbestiform properties, it is very possible to incorrectly conclude that "asbestos" has both oblique and parallel extinction angles. RJLG is unaware of any sample with macroscopic asbestiform properties that, when examined microscopically, had no particles with parallel extinction and no particles that exhibited asbestiform characteristics.

In EPA's El Dorado Hills air report, Lab/Cor included fibers identified as hornblende in the asbestos count. Hornblende is not a regulated mineral and is not found in the asbestiform habit. As pointed out by Region 9 in this response, significant concentrations of hornblende were in the soil.[19] The indices of refraction reported by Asbestos TEM Laboratory for the El Dorado Hills soil samples were in the range of hornblendes and outside the range typical of actinolite. Thus, there is no evidence to suggest that the soil samples analyzed by Asbestos TEM Laboratory or RJLG contain any asbestiform actinolite.

"The R. J. Lee Report also cites an unpublished 1980 draft report to support its contention that structures found in the EPA air samples are not asbestos, and ignores a subsequent 1981 published report by the same author that actually supports the EPA approach."

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[19] **[RJLG footnote]** From page 9 of the April 20 **EPA Response:**: "Both the laboratory performing EPA's El Dorado soil sample analysis and the laboratory which analyzed the EPA air samples noted significant quantities of hornblende in the samples".

RJLG Response: RJLG apologizes for any apparent misrepresentation, but Region 9 will have to be more specific. In the 1981 paper, Ring[54] finds that amphibole asbestos fibers have a preferred orientation in the TEM with more than 70 percent of the fibers lying near the (001) (010) direction. We see no difference in the published and unpublished versions of the paper. In the EPA El Dorado Hills Study, more than 50 percent of the measured zones were not those included in Ring's analysis of grunerite in either the 1980 or 1981 version of the paper.

The tendency for asbestos fibers to have a different preferred orientation than cleavage fragments is well recognized.[32] Cleavage fragments preferentially orient relative to their cleavage planes while asbestos fibers, which do not have cleavage surfaces, orient preferentially relative to major crystal faces. The difference in orientation is apparent as shown in A-1, which compares the stereographic projections of the crystal orientations reported by Lab/Cor with similar measurements for tremolite asbestos from Jamestown, California.

"The R. J. Lee Report Applies a Geologic Definition rather than a Public Health Definition to Characterize Microscopic Structures - The R. J. Lee Report relies heavily on the geologic distinction between asbestos fibers and cleavage fragments of the same dimensions,"

RJLG Response: Asbestos fibers and cleavage fragments do not have the same dimensions. Very few cleavage fragments longer than 5 µm have dimensions of asbestos fibers and very few asbestos fibers have dimensions of cleavage fragments.[20,21] Below 5 µm the distinction is smaller but still significant.

It is RJLG's understanding that the "public health definition" of asbestos is based on the geological/mineralogical definition of asbestos and not the ≥3:1 aspect ratio adopted for convenience in counting particles,[22,23] which has no medical significance. The

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[20] **[RJLG footnote]** Virta, R. L., Shedd, K.B., Wylie, A.G., Snyder, J. G. (1983). "Size and Shape Characteristics of Amphibole Asbestos (Amosite) and Amphibole Cleavage Fragments (Actinolite, Cummingtonite) Collected on Occupational Air Monitoring Filters," Aerosols in the Mining and Industrial Work Environment, Vol. 2, Chapter 47, p. 633-643.

[21] **[RJLG footnote]** A.G. Wylie (1988). "Discriminating Amphibole Cleavage Fragments from Asbestos: Rationale and Methodology ", Exposure Assessment and Control Asbestos/Other Fibrous Material, p. 1065 – 1069.

[22] **[RJLG footnote]** Walton, W. H. (1982). "The Nature, Hazards, and Assessment of Occupational Exposure to Airborne Asbestos Dust: A Review." Ann. Occup. Hyg.

[23] **[RJLG footnote]** Ilgren, E.B. (2004) "The Biology of Cleavage Fragments: A Brief Synthesis and Analysis of Current Knowledge," Indoor Build Environment, Vol. 13, pp. 343-356.

geological/mineralogical distinction between asbestos and nonasbestos amphiboles is well recognized. Asbestos analytical methods incorporate these distinctions in the physical characteristics of particles including the optical and electron optical properties of asbestos fibers and cleavage fragments.[24] The regulations regarding exposures to amphiboles and serpentines are based on the exposure to the asbestiform varieties of those minerals as defined geologically.[25]

"with the implication that exposure to cleavage fragments is benign and of little or no health significance. ***For the purposes of public health assessment and protection, EPA makes no distinction between fibers and cleavage fragments of comparable chemical composition, size, and shape."***

RJLG Response: Every EPA regulation concerning asbestos cites six asbestiform minerals. They do not include the nonasbestos analogues of those minerals or of any other amphibole. The intent of the regulations to exclude nonasbestos minerals is clear by the omission of antigorite, the nonasbestos analogue of chrysotile; cummingtonite-grunerite, the nonasbestos analogue of amosite; and riebeckite, the nonasbestos analogue of crocidolite. The use of PCMe structures defined solely by an overly inclusive aspect ratio criterion is insufficient to identify fibers and particles of "comparable chemical composition, size, and shape." Examination of the amphibole "fibers" counted in EPA's El Dorado Hills Study demonstrates that all of the reported amphibole "fibers" longer than 5 µm have widths greater than 90% of the tremolite asbestos structures reported in the Addison Davis[26] studies or in other studies of amphibole asbestos exposure, and far wider than found in lung burden analysis of amphibole asbestos exposures.[27] The data from such studies demonstrate that the exposure estimates in the EPA El Dorado Hills Study are not comparable or relevant to any historical epidemiology study.

"The EPA Region 9 approach, which is supported by most public health agencies and scientists, as well as the American Thoracic Society, is based on the following: (1) The epidemiologic and health

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[24] **[RJLG footnote]** Langer, A.M., R.P. Nolan, J. Addison (1991). "Distinguishing Between Amphibole Asbestos Fibers and Elongate Cleavage Fragments of Their Non-Asbestos Analogues." Mechanisms in Fibre Carcinogenisis, p. 253-267.

[25] **[RJLG footnote]** OSHA (1992). Preamble to Regulations, 57 FR 24310, June 8, 1992, http://www.osha.gov/SLTC/asbestos/standards.html.

[26] **[RJLG footnote]** Davis, J. M. G., J. Addison, C. McIntosh, B. G. Miller, K. Niven. "Variations in the Carcinogenicity of Tremolite Dust Samples of Differing Morphology." Annals New York Academy of Sciences, 1991, 643, pp. 473-489.

[27] **[RJLG footnote]** Pooley, F.D. & Clark, N.J. (1979). Fiber dimensions and aspect ratio of asbestos in lung tissue. Crocidolite, chrysotile, amosite particles determined in lung tissue specimens. Ann. of New York Academy of Sciences, Vol. 330, pp.711-716.

studies underlying EPA and Cal/EPA cancer risk assessment methods were based on exposures to both cleavage fragments and fibers, and were unable to distinguish between the two, (2) The most recent panel of experts to review asbestos risk assessment methods, the 2003 Peer Consultation Panel convened by EPA, concluded that "it is prudent at this time to conclude equivalent potency [of cleavage fragments and fibers] for cancer,"[28] ***(3) No well-designed animal or epidemiological studies have adequately tested the hypothesis that cleavage fragments with the same dimensions as a fiber are benign or that the human body makes any distinction,"***

RJLG Response: There is an extensive body of literature[29] that has shown that cleavage fragment populations have very different health consequences than asbestos fibers. After extensive hearings, OSHA concluded that cleavage fragments do not present the same risks as asbestos fibers.[25] Epidemiology studies conducted on a population of miners exposed to 40 – 60% tremolite cleavage fragments have shown no elevated asbestos health risk.[30]

"(4) Studies that purport to show that cleavage fragments are benign are questioned by many asbestos health experts,"

RJLG Response: This statement is irrelevant to the scope of RJLG's report and to its findings documenting data quality flaws and other errors in the EPA El Dorado Hills Study. RJLG was asked to review the EPA El Dorado Hills Study on the basis for which it was designed: to measure exposure to asbestos. RJLG found evidence that the study did not measure amphibole asbestos.

"(5) There are no routine asbestos air analytical methods, including those used by EPA, NIOSH, the Mine Safety and Health Administration (MSHA), the American Society for Testing and Materials (ASTM), and ISO which differentiate between cleavage fragments and crystalline fibers on an individual fiber basis."

RJLG Response: This statement is not correct. The EPA Yamate method[31] was specifically designed to differentiate amphibole asbestos from nonasbestos silicates including amphibole cleavage fragments. The Yamate method states that amphibole asbestos will have closely

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[28] **[EPA footnote]** USEPA (U.S. Environmental Protection Agency) (2003). Report on the Peer Consultation Workshop to Discuss a Proposed Protocol to Assess Asbestos-Related Risk, Final Report. Office of Solid Waste and Emergency Response, Washington D.C. Page viii.

[29] **[RJLG footnote]** Ilgren, E.B., "The Biology of Cleavage Fragments: A Brief Synthesis and Analysis of Current Knowledge," Indoor Build Environment, Vol. 13, pp. 343-356. October 2004.

[30] [**RJLG footnote]** Yasushi Honda M.D., Colleen Beall Dr. P.H., Elizabeth Delzell S.D., Kent Oestenstad Ph.D., Ilene Brill M.P.H., Robert Matthews B.S. (2002). "Mortality Among Workers at a Talc Mining and Milling Facility"; Ann. Occup. Hyg., Vol. 46, p. 575-585.

[31] [**RJLG footnote]** G. Yamate, S. C. Agarwal, R. D. Gibbons (1984). "Methodology for the Measurement of Airborne Asbestos by Electron Microscopy", IIT Research Institute, Contract No. 68-02-3266, July 1984.

spaced rows of spots with a 0.53 nm row spacing in the SAED pattern and that morphology is the ultimate determinant of whether the particle is asbestos or not since some portion of nonasbestos amphiboles will also show the 0.53 nm row spacing. MSHA published a method[32] which states: "Differentiation between asbestiform amphibole minerals and associated nonasbestos minerals can also be made by careful and critical inspection of the SAED pattern." ASTM has recently completed an updated PCM method[33] that allows routine screening for asbestiform versus nonasbestos particles.

"The R. J. Lee Report's "Virtual" Review of EPA Region 9's Air Samples is Inconsistent with Established Laboratory Practices *-The R.J. Lee Group did not have access to EPA's actual air samples, nor did it collect any air samples of its own.* ***Rather it reviewed limited pictures and spectra data of a small number of EPA's air samples and drew conclusions based on those representations. Such a virtual review is not consistent with the National Voluntary Laboratory Assurance Program (NVLAP) quality assurance procedures nor the verification methods of the National Institutes of Standards and Technology."***

RJLG Response: RJ Lee Group reviewed all of the count sheets provided by EPA, the dimensional data for all counted particles, and all produced Lab/Cor EDS and SAED patterns and photographs of counted structures. These were not a limited set of materials but a rather extensive set of documents.

RJLG's review of the data was consistent with NVLAP and NIST verification methods. RJLG reviewed the data in conformance with NIST procedures[34] and information that EPA made available. RJLG's findings are based on the data supplied by EPA. RJLG also requested that EPA provide splits of the actual samples for analysis by RJLG. The fact that RJLG did not analyze any air samples is due to the fact that EPA did not provide splits of the air samples as requested.

RJLG also notes for the record that EPA itself requested Trillium, Inc.[35] to conduct a similar "virtual review" of the PLM data for the soil

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[32] **[RJLG footnote]** R. L. Clark (1982). "MSHA Standard Method for Fiber Identification B[y] Electron Microscopy", Asbestos Standards: Materials and Analytical Methods, J. Small and E, Steel, eds., National Bureau of Standards, NBS Special Publication 619, p 207 – 210.

[33] **[RJLG footnote]** Standard Method for Sampling and Counting Airborne Fibers, Including Asbestos Fibers, In Mines and Quarries, by Phase Contrast Microscopy and Transmission Electron Microscopy, D7200.

[34] **[RJLG footnote]** S. Turner and E Small (1994). "Airborne Asbestos Method: Standard Test Method for Verified Analysis of Asbestos by Transmission Electron Microscopy – Version 2.0", National Institute of Standards and Technology, NISTIR 5351.

[35] **[RJLG footnote]** D. A. Sheppard (2005). "Data Review Summary – July 20, 2005, El Dorado Hills Naturally Occurring Asbestos Multimedia Exposure Assessment", Trillium document 001275.0440.01TA.

samples (analyzed by Asbestos TEM Laboratory, Inc.) that was based solely on the provided documents and did not include an independent analysis of samples or any reported conversation with the analytical laboratory. Thus RJLG's review of the data is consistent with accepted practices and consistent with EPA practices in this case.

"Federal Courts Have Supported EPA – ***Many of the assertions of the R. J. Lee Report are consistent with positions that the R.J. Lee Group took as an expert witness for W.R. Grace in the Libby, Montana litigation. In this litigation, the written opinions of the District and Appeals courts, while not specifically addressing the opinions of the R.J. Lee Group, rule in favor of EPA and expressly hold that EPA's experts and science are credible.[36]"***

RJLG Response: It is disingenuous of EPA to imply that a court has reviewed, much less indicated its approval of, the methodological approach Region 9 is pursuing with regard to evaluating NOA exposure and health risks in El Dorado Hills. The decision cited by EPA in its footnote merely states that the court found that EPA "did not ignore accepted scientific principles." This limited statement obviously does not equate to a holding that EPA's experts and science were credible. More importantly, as the court opinion notes, testing methodology and data analysis with regard to asbestos is exceedingly complex. Thus, the findings of a court with regard to a particular record developed by EPA in the context of asbestos exposure litigation arising from commercial mining operations simply are not relevant to the NOA policy debate and data quality issues arising in the context of the El Dorado Hills Study.

2.0 Background

"In October 2004, the EPA Region 9 Superfund site assessment program conducted an assessment of exposures to naturally occurring asbestos (NOA) in El Dorado Hills, California. Specifically, EPA Region 9 simulated the sports activities of children and adults at three schools and a community park and, using personal air monitors, measured asbestos levels in the breathing zones of participants. EPA Region 9 also collected samples of ambient air in the area of the sampling at the same time the simulations were conducted to serve as reference samples. The personal activity-based samples were then compared to the reference samples. The Asbestos Hazard Emergency Response Act (AHERA)[37] regulation Z-test for statistical significance was applied to determine whether there were any statistically significant differences between the personal exposure samples

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[36] **[EPA footnote]** See U.S. v. W.R. Grace, 280 F Supp 2d 1149 (2003): U.S. v. W.R. Grace, 429 F. 3d 1224, 1245 (9th Cir. 2005). (Although debate regarding testing methodology and data analysis is "exceedingly complex", EPA did not ignore accepted scientific principles.)

[37] **[EPA footnote]** The Asbestos Hazard Emergency Response Act (AHERA) was passed by Congress in 1986 to provide for the inspection and mitigation of asbestos in school buildings. Regulations implementing the Act were promulgated by EPA in 1987.

and the ambient reference samples. EPA Region 9 collected over 400 air samples and generated over 7000 data points. All of EPA Region 9's's analyses were conducted by accredited laboratories using recognized methods and procedures with strict quality assurance control, including blind performance samples to check analytical accuracy."

"Amphibole asbestos, which many health scientists consider to be even more toxic than chrysotile asbestos, was found in almost all the reference and activity-based samples."

RJLG Response: EPA's assertion that amphibole asbestos was found in almost all samples is incorrect. Populations of asbestos have well-established physical and morphological characteristics. The limited number of photographed particles and the length/width measurements of the entire population do not conform to these known characteristics. (See Attachment A-3, photographs produced by Lab/Cor). Moreover, the physical characteristics of the amphiboles in the source samples, the El Dorado Hills soil, did not meet the definition of asbestos under any PLM method, including EPA's PLM method. See Attachment A-4 for a comparison of the morphological characteristics of the particles in the El Dorado Hills soil, asbestiform particles from Harvard Way near the El Dorado Hills test site and Jamestown, CA. Additional images documented by RJLG are included in Attachment A-4a (a separate document) which includes RJLG images of particles imaged by TEM and field emission scanning electron microscopy (FESEM) together with corresponding energy dispersive x-ray (EDS) spectra and selected area electron diffraction (SAED) patterns. These data clearly demonstrate that elongated particles observed in the El Dorado Hills soil samples do not have the same characteristics of those of asbestiform amphiboles (e.g., Harvard Way, Jamestown).

"Of the 29 different sets of activity-based scenario measurements, application of the Z-test determined that personal exposures from 24 scenarios were significantly elevated over the reference samples."

RJLG Response: The Z-test was designed for comparison of air samples collected at the completion of an asbestos abatement and requires that all air samples have the same analytical sensitivities, the same number of counted grid openings, and the same amount of air volume sampled. Without further information, RJLG is unable to evaluate whether EPA's application of the Z-test in these comparisons was appropriate. In our view, a more appropriate test is a statistical comparison of the Berman-Crump[16] concentrations – as these fibers are of the dimensions most closely linked with risk of asbestos disease.

"Most importantly, the data showed that children and adults participating in sports activities in areas where asbestos occurs naturally in the surface soils, as it does in El

Dorado Hills, can be exposed to asbestos fibers of health concern at up to 62 times the corresponding reference levels."

RJLG Response: The Lab/Cor data are of questionable value for making a determination of increased exposure above reference levels. The quality and reproducibility of the fiber counts alone indicates this assessment by EPA is faulty. The findings that hornblende minerals were counted as "asbestos fibers of health concern," absent any data to suggest these fibers do have a health concern, also indicates this assessment is incorrect.

"EPA Region 9 released the data from the assessment in May 2005 and held a public meeting in El Dorado Hills that was attended by more than 1000 members of the public. From the outset of the assessment, EPA Region 9 made clear to the community that EPA's only intent was to gather data on potential exposures. The community and the State and local regulatory agencies could then use the information to make decisions about the significance of those exposures and determine appropriate control measures. Both EPA Region 9 and the Agency for Toxic Substances and Disease Registry (ATSDR) have informed the community that exposure levels are a main determinant of the risk of developing asbestos-related cancers and non-cancer diseases, and that reducing the exposures reduces the risk. Consistent with its intent, EPA Region 9 has actively engaged the State and local regulatory agencies to improve naturally occurring asbestos mapping, monitoring, dust control, and regulation. El Dorado County has recently adopted more stringent dust control ordinances."

3.0 Detailed Comments on the R. J. Lee Report

3.1 R.J. Lee Finding #1:"Based on Mineralogy, Sixty-Three Percent (63%) of the Amphibole Particles Identified as Asbestos Fibers can not be Asbestos."

"The R. J. Lee Report argues that there is too much aluminum in 63% of EPA Region 9's identified fibers for the fibers to be asbestiform.[38] In addition, the remaining 37% (sometimes the Report uses 35%) are not asbestos fibers based on their particle dimensions."

EPA Response:

"Aluminum - Analysis of the EPA Region 9 El Dorado air samples was performed using the International Standards Organization (ISO) method 10312, a state-of-the-art Transmission Electron Microscope (TEM)[39] method with energy dispersive spectroscopy (EDS)[40] that has strict counting rules and characterizes the dimensions and chemistry of every fiber identified by the

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[38] **[EPA footnote]** Asbestiform: Having the form or structure of asbestos.

[39] **[EPA footnote]** Transmission Electron Microscopy (TEM) produces images of a sample by illuminating the sample with an electron beam in a vacuum, and detecting the electrons that are transmitted through the sample.

[40] **[EPA footnote]** Energy Dispersive Spectroscopy (EDS) uses measurement of the energy and intensity of X-rays generated when a selected area of a sample is irradiated with an electron beam to identify the mineralogical composition of a structure.

microscopist. Identification of fiber type was performed according to the general guidelines of the International Mineralogical Association (IMA) (Leake, 1997)[41], the international standard for amphibole nomenclature. This same approach for asbestos classification is recommended in the "Research Method for Sampling and Analysis of Fibrous Amphibole in Vermiculite Attic Insulation", EPA 600/R-04/004, January 2004, and was one of the tools used by Meeker et al (2003)[42] to determine the composition and morphology of amphiboles from Libby, Montana."

RJLG Response: Neither the Meeker nor the 'Attic Insulation' methods use the Leake/IMA method to identify or classify asbestos. The Leake/IMA method is used for identifying a mineral but does not classify the mineral's habit and thus, does not distinguish between the asbestiform and nonasbestiform habits of minerals and cannot be used to classify asbestos. Mr. Meeker recognizes that specific mineral habits exist and that tremolite and actinolite can occur in different mineral habits. Meeker also recognizes that RJLG's argument is a generally observed condition (i.e., that asbestos amphiboles contain little or no aluminum) but takes exception as to whether it is a "mineralogical fact."

"The R. J. Lee Report claims that 63% of the amphibole fibers identified by the EPA laboratory[43] as actinolite asbestos have concentrations of total aluminum that are too high to form asbestos fibers. According to page 2 of the R. J. Lee Report, "Particles with more than 0.3 aluminum atoms pfu [per formula unit] or about 1.5 percent Al_2O_3 cannot form in the asbestos habit due to crystal lattice constraints." ***To support its argument, the R. J. Lee Report cites three references. However, on close examination, two of the three references do not agree with the upper threshold limit that the R.J. Lee Group puts on total aluminum content (Leake et al, 1997) (Deer, Howie and Zussman, 1997)[44]. "The third reference (Verkouteren & Wylie, 2000)[45] draws its conclusions on examination of a small set of fibrous actinolite asbestos samples which the authors partition into asbestos and fibrous "non-asbestos" byssolite using criteria which the IMA specifically recommends against, and which is inconsistent with all standard asbestos analytical methods."***

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[41] **[EPA footnote]** B.E. Leake et al (1997). Nomenclature of Amphibole: Report of the Subcommittee on Amphiboles of the International Mineralogical Association, Commission on New Minerals and Mineral Names. American Mineralogist, Volume 82, pages 1019-1037.

[42] **[EPA footnote]** G.P. Meeker et al (2003). The Composition and Morphology of Amphiboles from the Rainy Creek Complex, Near Libby, Montana. American Mineralogist, Volume 88, pages 1955-1969.

[43] **[EPA footnote]** In this document, the terms "EPA laboratory" and "EPA Region 9 laboratory" refer to the private laboratories that conducted the analysis of the EPA soil and air samples under contract to EPA Region 9.

[44] **[EPA footnote]** W.A. Deer, R.A. Howie, and J. Zussman (1997). Rock-Forming Minerals: Double Chain Silicates, Vol 2, second edition, p 137 - 145.

[45] **[EPA footnote]** J.R. Verkouteren and A.G. Wylie (2000). The Tremolite-Actinolite-Ferro-Actinolite Aeries: Systematic Relationships Among Cell Parameters, Composition, Optical Properties, and Habit, and Evidence of Discontinuities. American Mineralogist, 85, p. 1239 - 1254.

RJLG Response: As noted above, Leake/IMA does not address the aluminum content of asbestos, it only identifies the name of the amphibole mineral being evaluated. Deer et al[44] note (page 141) that in "most tremolite-actinolites, the replacement of Si by Al is small (<0.3 Al pfu)" and (page 182) that "Electron probe analyses showed that specimens that contain more than a very small amount of aluminum do not have asbestiform habit." Deer cites Dorling and Zussman[46] for the low aluminum content. Dorling and Zussman[46] show (Figure 16 of their paper) that aluminum atoms in the asbestos samples analyzed were present at less than 0.1 apfu. The Dorling findings were supported by Verkouteren and Wylie[45] who showed 85% of their asbestos samples contained 0.1 Al apfu or less. Verkouteren and Wylie[45] classified the fibrosity of minerals using accepted morphological criteria and found those which were asbestos did not contain significant aluminum. Verkouteren and Wylie's[45] description of the nonasbestos samples, while useful to establish the scientific principals involved, have nothing to do with IMA naming conventions or any standard analytical method.

Mr. Meeker agreed with RJLG on the aluminum content of asbestos as a general proposition but suggested that in the case of naturally occurring asbestos there could be exceptions. RJLG evaluated this suggestion by obtaining and analyzing asbestiform tremolite/actinolite samples from Harvard Way near the EPA El Dorado Hills test site and from nearby San Andreas, CA. The asbestiform particles contain much lower quantities of aluminum than the amphibole particles in the soil samples from the El Dorado Hills Study. Attachment A-5 compares the aluminum content measured by RJLG in amphibole particles in the soil from El Dorado Hills with the aluminum content found in asbestiform amphibole particles collected at Harvard Way and nearby San Andreas. The latter two are similar to the aluminum content reported for the actinolite and tremolite in the NIST SRM 1867a (from Barstow, CA) and in the reported aluminum content of the Jamestown tremolite asbestos used in the Addison Davis Study.[26] Thus, Mr. Meeker's suggestion that El Dorado may be an exception to the general rule is unsupported by the analysis of asbestiform fibers from the same locality as the El Dorado Hills samples or by the analysis of other asbestiform tremolite from California.

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[46] **[RJLG footnote]** M. Dorling and J. Zussman (1987). "Characteristics of asbestiform and non-asbestiform calcic amphiboles", Lithos, 20, p. 469-489.

*"Perhaps most important is the fact that all three references agree that it is the **IMA criteria which primarily govern the general classification of amphibole type, not the total aluminum content."***

RJLG Response Again as noted previously, Leake/IMA only classifies amphibole minerals according to the chemical content and does not identify whether they are asbestiform or not. Thus, Leake/IMA can serve to indicate whether an amphibole is of the type that would be regulated as asbestos if it is in the asbestiform habit, but it cannot indicate whether the amphibole is asbestiform or nonasbestiform.

"These references therefore actually support the classification approach taken by the EPA laboratory."

*"The R.J. Lee Group did not have access to the EPA air samples to conduct their own analyses. Instead, the R.J. Lee Group looked at a limited number of photographs of the recorded EDS spectra. Interferences by other elements in the sample can affect the aluminum total in the spectra. This is especially important because the EPA samples were of air releases from soil, not processed asbestos material. **Soils contain nonasbestos mineral and biological particles that can influence element totals in an EDS spectrum, most notably clay particles, which are high in aluminum."***

RJLG Response: RJLG found no evidence of clay contamination that would interfere with the TEM analysis on the amphibole particles in the soil samples from the El Dorado Hills Study. (see Attachment A-6). If the analyst believed the presence of clays or other minerals caused an interference, Lab/Cor should have taken appropriate steps to make background subtractions and should not have used the direct results of the analysis to identify the mineral.

RJLG examined samples of El Dorado Hills soil by X-ray diffraction and computer-controlled scanning electron microscopy. The results indicate that the soil is comprised of chlorite, hornblende, quartz, sepiolite, muscovite, and other minerals. Any particles coating the amphibole particles would also have contained additional quantities of magnesium, silica, and iron. Thus RJLG did not find evidence to support Mr. Meeker's assertion that the aluminum could have come from a coating.

"The laboratory used by EPA Region 9 identified aluminum-rich actinolite asbestos, by applying the IMA classification guidelines to its direct analysis of the actual sample.[47]"

RJLG Response: With over 30 years of experience in asbestos characterization analysis, and familiarity with the literature concerning asbestos

[47] **[EPA footnote]** Personal communication with John Harris, Lab/Cor, January 2006.

characterization, RJLG is unaware of any aluminum-rich actinolite or tremolite asbestos. In addition, the elemental analysis performed by Lab/Cor to determine the IMA mineral classification used normalized energy dispersive spectroscopy (EDS) data. Normalization of elemental concentrations performed as part of an EDS analysis is known to result in an over-estimation of the silicon concentration in silicate minerals which can have a dramatic effect when assigning amphibole mineral nomenclature. In this situation, the effect of Lab/Cor's normalization procedures on the El Dorado sample EDS data was to misclassify hornblende particles as actinolite (see Attachment A-7). There is insufficient supporting documentation in the Lab/Cor data to ascertain the degree of error in their EDS concentrations. Thus there is a very high degree of uncertainty in the mineral assignments made by Lab/Cor.

"Particle Dimension -As previously stated, the R. J. Lee Report claims that 37% of the fibers counted by EPA in the El Dorado Hills air samples are not asbestos fibers based on their particle dimensions. ***The report claims that EPA Region 9 inflated the fiber counts by including asbestos structures which do not meet the definition of a fiber as described in ISO 10312. The general ISO 10312 method requires the counting of every asbestos structure with a length to width aspect ratio of 5:1 or greater."***

RJLG Response: The ISO 10312 method represents an attempt by the international community to standardize a method for asbestos analysis and counting for use in environments where the binding of commercial asbestos fibers in complex matrices and structures was believed to be inadequately dealt with by earlier methods. The ISO 10312 method adopted the 5:1 aspect ratio because it was recognized that use of a ≥3:1 aspect ratio resulted in the incorporation of many nonasbestos particles into the count. ISO 10312 was designed to be flexible and, therefore, the method recognizes that variation of the counting rules is acceptable and conforms to the other requirements of the method provided the variation is noted as an exception. Thus, while the ISO 10312 method permits modification to use the ≥3:1 aspect ratio, it also requires that the modification be acknowledged as it has the result of including many nonasbestos particles in the exposure estimates. EPA did not acknowledge its modification or its data quality impacts.

"As directed by Region 9, the EPA laboratory counted structures with a 3:1 or greater aspect ratio. The R. J. Lee Report states that EPA erred in counting structures with aspect ratios less than 5:1."

"Annex C and Annex E of the ISO method clearly authorize the counting of PCME structures with a 3:1 aspect ratio if the data are to be used for exposure or risk assessment purposes, the stated goal of the El Dorado Hills assessment. In fact, the ISO method contains numerous

references to PCME fibers. PCME fibers are defined as fibers greater than 5 microns in length, and 0.25 to 3 microns in width with a 3:1 aspect ratio.[48] ***PCME fibers form the basis for EPA's IRIS toxicity database and the asbestos risk models of California EPA and other federal and international organizations.***[49]***"***

RJLG Response: PCMe fibers do not form the basis of IRIS risk models. Optically determined PCM structures in environments where commercial asbestos was being handled form the basis of the risk models. PCMe structures represent the fraction of PCM visible structures at 1000X magnification that are regulated minerals. The NIOSH 7402 method specifically requires that a TEM supplement to the 7400 method be conducted at 1000X magnification, and then the determination made to evaluate the fraction of TEM PCMe fibers that are asbestos. In an accurate analysis of airborne asbestos concentration, PCMe fibers should represent the fraction of asbestos fibers in the population of PCM fibers using the chemical, crystal structure and morphological properties to distinguish asbestos from nonasbestos countable structures. A more complete description of risk models is contained in a document prepared by Dr. Berman.[50]

"The R.J. Lee Group also manipulates its statistical analysis of the El Dorado Hills air data by ignoring counts of asbestos fiber bundles in its evaluations."

RJLG Response: This statement by EPA is not correct; bundles were not excluded from RJLG's analyses of fiber concentration. RJLG computed the size distribution of fibers excluding bundles to determine whether the particle population had the recognized dimensional characteristics of asbestos. This is in conformance with similar analysis by Burdett.[13] There was insufficient information in the Lab/Cor data to assess the

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[48] **[EPA footnote]** World Health Organization (1986). Environmental Health Criteria 53, International Programme on Chemical Safety, Asbestos and Other Natural Mineral Fibres, section 2.3.2.2.

[49] **[EPA footnote]** The IRIS asbestos cancer inhalation unit risk, a measure of asbestos cancer potency, is based on the EPA 1986 Airborne Asbestos Health Assessment Update (EPA/600/8-84/003F; 1986). Cal/EPA used a similar approach and data sets to derive its cancer unit risk. Both the IRIS and the Cal/EPA cancer potency values rely on human epidemiological studies that were conducted using phase contrast microscopy (PCM) analytical methods (some were midget impinger data converted to PCM counts) that could not distinguish fibers that were 5 microns in length or less. PCM cannot distinguish between fibers and cleavage fragments. PCM is not as powerful as current Transmission Electron Microscope (TEM) methods (400X vs 20,000X) as TEM can see the thinner/shorter fibers. However, since EPA's (and Cal/EPA 's) toxicity database relies on human health studies that used PCM, current EPA risk procedures use the more powerful TEM method but report the PCM equivalent (PCME) fibers and only use the PCME counted fibers in a risk assessment. This is because the IRIS asbestos file specifies that only PCME fiber counts be used with inhalation unit risk for risk calculation. See also the reference cited in footnote 11.

[50] **[RJLG footnote]** D. W. Berman (2006). Evaluation of the Approach Recently Proposed for Assessing Asbestos-Related Risk in El Dorado County, California. Report to the NSSGA.

method used by Lab/Cor to report the dimensions of apparent bundles.

"Bundles are two or more attached parallel asbestos fibers which can have a significant health impact when they are inhaled and separate into individual fibers. Bundles were counted in the historical epidemiological studies which form the basis of our knowledge of asbestos-related health effects and EPA's IRIS database. All of the established EPA, NIOSH, and ISO analytical methods require the counting of asbestos bundles, recognizing the significance of bundles to proper characterization of asbestos fiber levels."

"The R. J. Lee Report further states that EPA's data inflated the asbestos fiber count by ignoring the Agency's own "definition" of asbestos. To support this claim, the R.J. Lee Report cites the glossary of "Method for Determination of Asbestos in Bulk Building Materials", EPA 600/R-93/116, 1993, which states, in part, "With the light microscope, the asbestiform habit is generally recognized by the following characteristics: Mean aspect ratios ranging from 20:1 to 100:1 or higher for fibers longer than 5 microns." The building material analytical method is designed to detect commercially processed asbestos in items like floor tiles, roofing felts, paper insulation, paints, and mastics, not naturally occurring asbestos on air filters or in soil samples. ***To present the 20:1 aspect ratio for commercial grade asbestos as a universal EPA policy, and to advocate its use as an appropriate standard for analyzing air samples of naturally occurring asbestos is inappropriate and contradictory to use of the PCME dimensional criteria as a tool for assessing exposure risk."***

RJLG Response: RJLG did not present the definition of asbestos in EPA's Method 600/R-93/116 as a universal policy but merely cited the definition to show that the agency has recognized that asbestos aspect ratios are typically quite high, so much so that 20:1 is used to define the lower end of the aspect ratio for asbestos. It should be noted that asbestiform fibers observed in epidemiology studies conform to this definition. The same definition RJLG used is recited in the NIST Certificate for NIST SRM 1867a for uncommon commercial asbestos. Thus, the ≥3:1 aspect ratio used by Region 9 is inconsistent with basic and well-established understandings of the typical ranges of asbestos fiber aspect ratios, whether considering commercial or noncommercial asbestos fibers. However, as illustrated by Beard,[51] Wylie,[21] the EU study,[9] the Bureau of Mines,[12] and Campbell,[52] the 20:1 aspect ratio for fibers longer than 5 μm is a dimensional property consistent with the

[51] **[RJLG footnote]** Michael E. Beard letter dated 11/03/92 to Sally A. Sasnett of the USEPA (United States Environmental Protection Agency) regarding: Definitions used to define Asbestos Fibers / Asbestos Cleavage Fragments / Aspect Ratios

[52] **[RJLG footnote]** Campbell, W. J., R. L. Blake, L. L. Brown, E. E. Cather, J. J. Sjoberg (1977), 'Selected Silicate Minerals and Their Asbestiform Varieties - Mineralogical Definitions and Identification-Characterization', Bureau of Mines, United States Department of Interior, Information Circular 8751, pp. 1-55.

observations of asbestiform populations whether or not they are commercially exploited.

"The R. J. Lee Report also states that the diffraction pattern analyses produced by the EPA laboratory for the El Dorado Hills air samples demonstrate that the particles identified by the laboratory are not asbestos.[53] The report cites a 1980 unpublished draft study by S.J. Ring to support its conclusion. The R. J. Lee Report does not mention a 1981 published article by the same author which revises the findings such that they no longer support the conclusion of the R. J. Lee Report and, in fact, support the data produced by EPA.[54]"

RJLG Response: In the 1981 paper, Ring[54] finds that amphibole asbestos fibers have a preferred orientation in the TEM with more than 70 percent of the fibers lying near the (001) (010) direction. We see no difference in the published and unpublished versions of the paper. In the El Dorado Hills Study, more than 50 percent of the measured zones were not those included in Ring's analysis of grunerite in either the 1980 or 1981 version of the paper.

3.2 "R.J. Lee Finding #2:"The Laboratory Procedures did not Comply With the NVLAP Quality Assurance Standard." The R. J. Lee Report says that the false positive rate in our air samples was 35% when the acceptable limit in the National Voluntary Laboratory Accreditation Program (NVLAP) is 10%."

EPA Response:

"The laboratories used by EPA Region 9 for analysis of the El Dorado Hills air and soil samples are accredited through the National Voluntary Laboratory Accreditation Program (NVLAP). NVLAP is administered by the National Institute of Standards and Technology, a non-regulatory agency within the U.S. Commerce Department. A large part of the accreditation process involves on-site audits performed by NVLAP-certified inspectors who review laboratory operational and quality assurance compliance parameters, including documentation proving compliance with NVLAP requirements for verification analyses. A laboratory must demonstrate that all analysts reporting data meet the false negative and false positive requirements set forth by NVLAP before an accreditation certificate is issued. ***To make a determination that a laboratory did not comply with NVLAP verification standards would require a very detailed examination of all laboratory generated raw data, project specific information, such as a site-specific EPA issued Quality Assurance Project Plan, laboratory instrument log books, and other data and information not supplied in an analytical report. Interviews with the***

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[53] **[EPA footnote]** Diffraction pattern analyses irradiates a sample with x-rays and then takes an x-ray photograph.

[54] **[EPA footnote]** S.J. Ring (1981). Identification of Amphibole Fibers, Including Asbestos, Using Common Electron Diffraction Patterns. In Russell P.A. and Hutchings A.E. (Eds), Electron Microscopy and X-ray Applications to Environmental and Occupational Health Analysis, Vol. 2:175-198, Ann Arbor Science Publ., Inc.

laboratory manager, quality assurance manager, and involved analysts are also mandatory to make judgment on a laboratory's possible non-compliance. The R.J. Lee Report's conclusion that the EPA laboratory was not in compliance with NVLAP, based on a cursory review of count sheet and other limited data without the in-depth examination detailed above, is therefore invalid and cannot be used to question EPA's analytical results."

RJLG Response: RJLG concluded that the verified counting results produced in the EPA El Dorado Hills Study did not meet the reproducibility requirements of the NVLAP standards. This is indisputable. Whether this occurrence places a laboratory in violation of its NVLAP certification is outside the purview of RJLG. It is worth noting that the laboratory counts would be considered to be in non-conformance with the verification standards as presented in EPA's QAPP for Libby.[55] RJLG's procedures were the same as those of Trillium (an EPA contractor in this project) who performed a "virtual review" of the PLM soil data."

"EPA chose NVLAP-accredited laboratories for the El Dorado Hills assessment as a minimum quality requirement. For supplemental quality assurance, the laboratories were subjected to on-site audits performed by EPA's Quality Assurance Technical Support group, and both laboratories were sent performance evaluation samples prior to analysis of the El Dorado samples. In addition, the laboratory conducting the air sample analysis was sent double blind performance evaluation samples during the sampling event. In all cases, the laboratories successfully identified the amounts and types of asbestos present on the blind samples within acceptable limits. ***Further, the El Dorado Hills air and soil data were validated by a third party in accordance with standard EPA quality assurance procedures and were found to be acceptable for all uses."***

RJLG Response: RJLG did not receive copies of any data validation performed by a third party on the air sample data and cannot comment on its significance.

3.3 R. J. Lee Finding #3:"The Soil Samples do not Demonstrate the Presence of Amphibole Asbestiform Minerals."

"The R. J. Lee Report states that the actinolite asbestos fibers identified in the El Dorado Hills soil samples contain too much aluminum to be asbestiform and that the extinction angles of the fibers indicate that they are non-fibrous cleavage fragments. The R.J. Lee Group's analysis of 23 split soil samples from EPA's October 2004 sampling event found no asbestos in the samples."

[55] **[RJLG footnote]** P. Peronard and C. Weiss (2001). Phase 2 Sampling and Quality Assurance Plan, Revision 0. EPA Region 8, page 31 ("Number of fibers within each grid opening: must be the same", ftp://ftp.epa.gov/eprps/libby/Libby-P2-QAPP-Pt1.pdf.

EPA Response:

"Aluminum - The R. J. Lee Report states that the aluminum content of the fibers in the soil samples was too high to be asbestiform actinolite and that it was indicative of nonasbestiform actinolite and another amphibole, hornblende, which contains approximately 10-20% by weight Al_2O_3 (5.3-10.6% by weight aluminum). Both the laboratory performing EPA's El Dorado soil sample analysis and the laboratory which analyzed the EPA air samples noted significant quantities of hornblende in the samples, but did not count or report those particles as asbestos."

RJLG Response: Despite EPA's unsupported statement above, RJLG found that the particles Lab/Cor identified as hornblende, edenite, were in fact included in the asbestos count (Figure 1). Other particles, which contained significant concentrations of aluminum and for which hornblende gave the best fit to the SAED pattern, were reported as actinolite and counted as asbestos by Lab/Cor.

A	13	A1	CM	9	10	F	0.75	0.05	15			Chrysotile	TAS_AHRA
A	13	A1	AZQ	10	11	F	1	0.2	5.0	5280	585	Mg, Al, Si, Ca, Fe Actinolite	TAS_AHRA
A	14	D11	AQ	11		MD1-1	20	15	1.3			Edenite	TAS_AHRA, AS>5_AHRA, AS>10_AHRA
A	14	D11	AQ		12	MF	15	2	7.5			Na, Mg, Al, Si, Ca, Fe Edenite	PCMEF-US
A	15	D31	CM	12		MD1-0	8	8	1.0			Chrysotile	AS>5, TAS_AHRA, AS>5_AHRA

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Figure 1. A portion of the count sheet from sample CC2-L6-1CA-100504 illustrating Lab/Cor counted hornblende minerals (Edenite) as part of their analyses. A matrix fiber (MF) that was identified as "Edenite" and was 15 µm long and 2 µm wide was counted, classified as a PCMe fiber (PCMEF-US), and included in the calculation for PCMe concentrations.

Further, as noted previously in our discussion above under Finding #1, Deer et al[44] note (page 141) that in "most tremolite-actinolites, the replacement of Si by Al is small (<0.3 Al pfu)" and (page 182) that "Electron probe analyses showed that specimens that contain more than a very small amount of aluminum do not have asbestiform habit." Deer et al[44] cites Dorling and Zussman[46] for the low aluminum content. Dorling and Zussman[46] show (Figure 16 of their paper) that aluminum atoms in the asbestos samples analyzed were present at less than 0.1 apfu. The Dorling findings were supported by Verkouteren and Wylie[45] who showed 85% of their asbestos samples contained 0.1 Al apfu or less. Verkouteren and Wylie[45] classified the fibrosity of minerals using accepted morphological criteria and found

those which were asbestos did not contain significant concentrations of aluminum.

"Extinction Angles** - The extinction angle of a fiber evaluated by polarized light microscopy is one of many criteria used to identify mineralogical composition. The extinction angle for amphibole asbestos fibers is the difference in degrees between the long axis of the fiber and the angle at which the fiber optically disappears (the polarization direction where the light passing through it becomes "extinct") when the fiber is rotated under a polarized light microscope. The R.J. Lee Report states that amphibole asbestos fibers have a zero-degree extinction angle and that non-asbestos cleavage fragments have non-zero extinction angles. **Therefore, because the EPA soil sample analysis reported extinction angles which, according to the R.J. Lee Group, averaged 12°, the report alleges EPA incorrectly identified cleavage fragments as asbestos fibers."

RJLG Response: Parallel extinction is one of the criteria, not the only criterion, used to classify a particle as asbestiform. The 12 degree "average" extinction angle was not determined by RJLG but was reported by Asbestos TEM Laboratory, Inc. Each and every sample was reported by Asbestos TEM Laboratory as having a 12 degree extinction angle and the exact same refractive indices. EPA's own PLM analytical method[56] (page 15) requires the optical properties of tremolite/actinolite asbestos to be measured when the fibers exhibit parallel extinction. The particles in the El Dorado Hills soil analyzed by RJLG had no characteristics of asbestiform particles including extinction characteristics.

The R.J. Lee Report's conclusion regarding extinction angles is contradicted by the National Institute of Standards and Technology (NIST) and the major analytical methods used for analysis of asbestos in soil and bulk samples.** NIST certifies and provides Standard Reference Materials (SRM) for laboratory instrument calibration and laboratory accuracy measurement. **The NIST Tremolite/Actinolite SRM 1867A is a special set of three samples certified by NIST to be of ultra-high purity tremolite, actinolite, and anthophyllite asbestos and is considered the "gold standard" for asbestos analytical laboratories. The material is rigorously characterized and is accompanied by a six-page document that describes the properties of each sample.

RJLG Response: There is a continuing difference of opinion relative to the oblique extinction angles reported in the El Dorado Hills Study. Region 9 relies on Mr. Meeker's suggestion that the NIST SRM 1867a is a "gold standard" for the extinction angle of tremolite and actinolite asbestos. Region 9 and Meeker compare the oblique extinction angles certified for the tremolite/actinolite in the NIST SRM 1867a with the oblique extinction angles reported by Asbestos TEM Laboratory for particles

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[56] **[RJLG footnote]** R. L. Perkins and B. W. Harvey. Method for the Determination of Asbestos in Bulk Building Materials, U.S. Environmental Protection Agency, EPA/600/R-93/116, July 1993.

in the El Dorado Hills soil. RJLG does not believe that NIST SRM 1867a should be cited as certifying the extinction angles of asbestos. The optical properties listed in the NIST certificate[57] were measured on "*larger, single crystal fibers,*" not asbestos fibers (page 3 of certificate). The NIST certificate notes that only "*some portion of the standard is asbestiform.*" The NIST certificate also states that "*the unique morphology of asbestos may alter the properties of tremolite, actinolite, and anthophyllite asbestos from those reported for the materials contained in this SRM, as described in Reference 4 (Verkouteren).*"

The NIST certificate[58] does not purport that NIST SRM 1867a is pure asbestos. Examination of the particles in the NIST SRM 1867a standard demonstrates that a substantial portion of the particles have obvious characteristics of cleavage fragments. Thus a general description of the range of extinction properties of the reference material cannot be used to identify the extinction angles of asbestos particles in the sample.

RJLG characterized samples of naturally occurring asbestos from Jamestown, California, El Dorado County, San Andreas, California, and the NIST SRM 1867a by PLM. In each of the samples, particles that had two or more of the physical characteristics of asbestos as described in the EPA method and by Wylie[21], were compared with particles that had the characteristics of cleavage fragments.[52] In every case, including the NIST standard, the vast majority of particles having asbestos characteristics showed parallel or near parallel extinction while the cleavage fragments and needle-like particles predominantly had oblique extinction greater than 10 degrees. Attachment A-8a (a separate document) shows photographs of particles from each sample and gives their related extinction angles.

"*It is required that all analytical laboratories accredited by NIST/NVLAP have the material in their possession and that they use it to calibrate their operations and to test their analysts. The NIST SRM 1867A certificate which accompanies the samples of tremolite and actinolite states that the reference tremolite can have an extinction angle of up to 16.6 + 0.3^{o} and that the actinolite can have an extinction angle of up to 15.9+0.2^{o}.* ***When the EPA laboratory processed the NIST actinolite standard in the manner of the El Dorado Hills soil samples, the extinction angles of the fibers in the processed standard sample were consistent with allowed***

[57] **[RJLG footnote]** The certificate indicates the 20% of the fibrous material in the actinolite sample is not actinolite and that an undisclosed portion of the overall sample is not fibrous ("A considerable amount of material may be massive.").
[58] **[RJLG footnote]** NIST SRM 1867 and 1867a Certificate of Analysis.

maximum extinction angles for tremolite/actinolite asbestos (~ 10° to 20°) and the extinction angles of the fibers seen in the EPA soil samples.[59]"

RJLG Response: EPA is incorrectly using the maximum measured extinction angles of the NIST SRM 1867a as the sole criterion for determining that the reported amphibole particles in the El Dorado Hills soil samples are asbestos. EPA's PLM method[60] and the OSHA ID 191[61] method define the characteristics of asbestos fibers as "high aspect ratio, flexible, splayed ends, parallel sides." Every asbestiform population shows these characteristics. Unprocessed asbestos samples are also likely to include prismatic and acicular needle-like particles that are not asbestiform. The amphiboles in every soil sample in the El Dorado Hills data set were described by EPA's laboratory as having 12-degree extinction angles and needle-like particles. Needle-like particles having oblique extinction are not regarded as asbestiform.[52] The characteristics of asbestiform populations are defined in PLM methods and always refer to high aspect ratio, curvature, splayed ends, and parallel sides. Furthermore, the indices of refraction in the El Dorado Hills soil particles do not match the indices in the NIST SRM 1867a standard. As pointed out by Addison,[18] the indices of refraction of the soil particles are characteristic of hornblende or ferro-hornblende, not actinolite.

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[59] **[EPA footnote]** M. Bailey (2006). Identification of Asbestiform Tremolite/Actinolite. Naturally Occurring Asbestos Workgroup Meeting Presentation.

[60] **[RJLG footnote]** EPA 600/R-93/116, In particular, these characteristics are more important than extinction angle: page A-1, "If a sample contains a fibrous component of which most of the fibers have aspect ratios of < 20: 1 and that do not display the additional asbestiform characteristics, by definition the component should not be considered asbestos."

[61] **[RJLG footnote]** OSHA ID 191, section 3.5: "Asbestos fibers are very long compared with their widths. The fibers have a very high tensile strength as demonstrated by bending without breaking. Asbestos fibers exist in bundles that are easily parted, show longitudinal fine structure and may be tufted at the ends showing "bundle of sticks" morphology. In the microscope some of these properties may not be observable. Amphiboles do not always show striations along their length even when they are asbestos. Neither will they always show tufting. They generally do not show a curved nature except for very long fibers. Asbestos and asbestiform minerals are usually characterized in groups by extremely high aspect ratios (greater than 100:1). While aspect ratio analysis is useful for characterizing populations of fibers, it cannot be used to identify individual fibers of intermediate to short aspect ratio. Observation of many fibers is often necessary to determine whether a sample consists of "cleavage fragments" or of asbestos fibers. Most cleavage fragments of the asbestos minerals are easily distinguishable from true asbestos fibers. This is because true cleavage fragments usually have larger diameters than 1 µm. Internal structure of particles larger than this usually shows them to have no internal fibrillar structure. In addition, cleavage fragments of the monoclinic amphiboles show inclined extinction under crossed polars with no compensator. Asbestos fibers usually show extinction at zero degrees or ambiguous extinction if any at all. Morphologically, the larger cleavage fragments are obvious by their blunt or stepped ends showing prismatic habit. Also, they tend to be acicular rather than filiform."

"Further, the laboratory methods of EPA, NIOSH, and other agencies for analysis of asbestos in bulk material all state that tremolite-actinolite asbestos fibers may have zero (parallel) or non-zero (inclined or oblique) extinction angles. EPA Method 600/R-93/116[62], the standard method used by all NIST/NVLAP accredited laboratories to test building materials for the presence of asbestos, states in Table 2-2, Optical Properties of Asbestos Fibers, that tremolite-actinolite asbestos has extinction "parallel and oblique (up to 21°)." NIOSH Method 9002[63], the method used for analysis of the El Dorado Hills soil samples, states directly that actinolite and tremolite fibers exhibiting inclined extinction are to be considered asbestos. The method further states that "If anisotropic fibers are found (during PLM analysis), rotate the stage to determine the angle of extinction. Except for tremolite-actinolite asbestos which has oblique extinction at 10-20°, the other forms of asbestos exhibit parallel extinction...Tremolite may show both parallel and oblique extinction.[64]"

RJLG Response: EPA Region 9 points out contradictions in the language found in various methods. What EPA does not mention is that in EPA's own method, EPA 600/R-93/116, the analyst is specifically instructed to measure the index of refraction on particles showing zero extinction. In addition other PLM methods and the literature recognize that asbestos particles have parallel extinction. Verkouteren and Wylie[65] report that tremolite/actinolite asbestos fibers generally have parallel extinction, or in some cases, extinction less than 10 degrees. Addison[66] notes that the UK reference amphibole asbestos has parallel extinction, but that there are, just as noted by NIST for the NIST SRM 1867a, nonasbestos particles having oblique extinction. RJLG is not aware of any population of asbestiform amphiboles that do not display parallel extinction. In all known asbestiform amphibole populations, the vast majority of the amphibole asbestos fibers exhibit parallel extinction.

Mr. Meeker suggested that naturally occurring asbestos may not have the characteristics of commercial asbestos. RJLG evaluated this assertion for the asbestiform samples collected at Harvard Way near

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[62] **[EPA footnote]** USEPA (U.S. Environmental Protection Agency) (1993). Method for the Determination of Asbestos in Bulk Building Materials. EPA Method 600/R-93/116.

[63] **[EPA footnote]** NIOSH (National Institute for Occupational Safety and Health) (1992). Asbestos (Bulk) by PLM. Method 9002 (Issue 2).

[64] **[EPA footnote]** NIOSH (National Institute for Occupational Safety and Health) (1992). Asbestos (Bulk) by PLM. Method 9002 (Issue 2). Qualitative Assessment, Item c, page 4.

[65] **[RJLG footnote]** J. R. Verkouteren, A. G. Wylie (2002). "Anomalous optical properties of fibrous tremolite, actinolite, and ferro-actinolite," American Mineralogist, 87, p 1090-1095.

[66] **[RJLG footnote]** J. Addison (2006). Comments on the Report dated November 2005, by the RJ Lee Group of the 'Evaluation of EPA's Analytical Data from the El Dorado Hills Asbestos Evaluation Project' as presented by the EPA in the document 'El Dorado Hills, Naturally Occurring Asbestos Multimedia Exposure Assessment Preliminary Assessment and Site Inspection Report Interim Final", page 3.

one of the EPA test sites, at San Andreas, California, Jamestown, California, and the NIST 1867a sample. Attachment A-8 summarizes RJLG's extinction angle measurements performed on these samples. Attachment A-8a (a separate document) shows photographs of particles from each sample and gives their related extinction angles. For particles showing two of the morphological characteristics of asbestiform particles, 60-90 percent of the fibers had parallel extinction. Ninety percent (90%) of bundles having three or more asbestos characteristics cited in the NIST SRM 1867a had parallel extinction. Thus RJLG found no evidence to support Mr. Meeker's suggestion, and no evidence to support the findings by Asbestos TEM Laboratory that 185 samples contained asbestiform actinolite.

3.4 R.J. Lee Finding #4: "The ISO 10312 Analytical Method can not Distinguish Between Asbestos Fibers and Non-Asbestos Cleavage Fragments."

"The R.J. Lee Report states that the ISO 10312 method contains the disclaimer that "The method cannot discriminate between individual fibers of asbestos and non-asbestos analogues of the same amphibole material," and, therefore, EPA inflated the asbestos air concentrations by counting "cleavage fragments.""

EPA Response:

"The ISO 10312 method cannot differentiate between fibers and cleavage fragments with the same dimensions and chemical composition. No routine analytical method has a protocol for distinguishing fibers from cleavage fragments on an individual particle basis. Additionally, from a health standpoint, there is no evidence that supports making the distinction."

*"Cleavage fragment is a geologic term which refers to structures that form when nonfibrous forms of asbestos minerals split along crystallographic planes, as opposed to asbestos fibers which form from crystalline growth. The R.J. Lee Report maintains that there is a toxicological difference between asbestos structures which formed as fiber crystals and fibers which formed by cleavage plane separation. Page 3 of the R.J. Lee Report states that cleavage fragments are "not known to produce asbestos-like disease." **It is the position of EPA, the U.S. Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry (ATSDR) and National Institute for Occupational Safety and Health (NIOSH), and the American Thoracic Society, among others, that microscopic structures of amphibole and serpentine minerals that are asbestiform and meet the size definition of PCM fibers, should be counted as asbestos, regardless of the manner by which they were formed."***

RJLG Response: Asbestos structures are, by definition, formed as bundles of free, separable fibrils having a constant diameter, high aspect ratio, and the physical characteristics of asbestos fibers. Asbestos structures are not single crystals of irregular dimension produced by fracturing and separation along cleavage planes. The exemplar particles photographed by Lab/Cor and the size distribution of particles

classified as amphiboles in the El Dorado Hills Study are not indicative of asbestos fibers.

In effect Region 9 is broadening the definition of asbestiform to include all amphibole and serpentine structures that meet the counting criteria of a PCM fiber, regardless of how they were formed, whether by free crystal growth or by fracture of massive grains. EPA has only regulated six asbestiform minerals and has never regulated the nonasbestos analogues of those minerals or any other amphibole mineral.

The latter is a major change in regulatory policy. Non-reviewed commentary by peer consultation panel members is insufficient to arbitrarily extend the definition of asbestos to include all amphibole and serpentine cleavage fragments and thereby designate over 30% of the continental US as possibly containing "asbestos."

"There are four reasons why the health agencies have taken this position: (1) The epidemiologic and health studies underlying EPA, and California EPA, ***cancer risk assessment methods were based on exposures to both cleavage fragments and fibers, but were unable to distinguish between the two,"***

RJLG Response: It is not obvious what risk assessment methods Region 9 is referring to in this sentence but clearly the underlying epidemiology is based on exposures to commercially processed asbestos fibers. Processing ore in and of itself is designed to remove that portion of the ore that does not have the qualities of asbestos including portions of the host rock that may be nonasbestos amphibole or serpentine. The epidemiology studies (chrysotile miners) that would likely have included substantial populations of nonasbestos amphiboles or serpentine particles were excluded from consideration in the development of EPA's risk methodology because they did not conform to the dose/response characteristics reflected in the other epidemiology studies. The issues of risk assessment are more fully discussed by Dr. Wayne Berman.[50]

"(2) The most recent panel of experts to review asbestos risk assessment methods, the 2003 Peer Consultation Panel convened by EPA, concluded that "it is prudent at this time to conclude equivalent potency [of cleavage fragments and fibers] for cancer,[67]"

RJLG Response: The peer review panel recommended that cleavage fragments with the same dimensions as asbestos fibers should be treated as equally

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[67] **[EPA footnote]** USEPA (U.S. Environmental Protection Agency) (2003). Report on the Peer Consultation Workshop to Discuss a Proposed Protocol to Assess Asbestos-Related Risk, Final Report. Office of Solid Waste and Emergency Response, Washington D.C. Page viii.

potent. It is well known that nonasabestos particles >5 µm rarely have the same dimensions as asbestiform fibers. The peer review panel was addressing this issue within the context of the size range of structures being recommended by Berman and Crump[16]. They were not explicitly addressing the issue in the context of the PCMe exposure metric. Comparison of the width distribution of the El Dorado Hills particles with that of Jamestown asbestos tremolite or the asbestos distributions reported in the EU Report[68] or by Wylie[69] shows the El Dorado particles to be wider than those shown to cause disease (See Attachment A-9).

"(3) No well-designed animal or human epidemiological studies have been conducted to date to test the hypothesis that cleavage fragments with the same dimensions of a fiber are benign, or that the human body makes any distinction, and studies that purport to show that cleavage fragments are benign are questioned by many asbestos health experts,[70]"

RJLG Response: Cleavage fragments of the same dimension as asbestos fibers occur only rarely in particles longer than five µm. It may be prudent to construe such particles as having the same toxicity as asbestos fibers but such an opinion is beyond the scope of RJLG's expertise. Of relevance here is that asbestos fibers are long and thin, not short and fat, as were the particles classified as asbestos in the EPA El Dorado Hills Study. Cleavage fragments have not grown geologically as fibers with free surfaces as have asbestos fibers.

"(4) There are no routine air analytical methods, including those used by EPA, NIOSH, the Mine Safety and Health Administration (MSHA), the American Society for Testing and Materials (ASTM), and the ISO which differentiate between cleavage fragments and crystalline fibers."

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[68] **[RJLG footnote]** Schneider, T., Jorgensen, O., Sethi, S.A., Davies, L., Maclaren, W., Buchanan, D., Kidd, M., Burdett, G., Tempelman, J., Paoletti, L., "Development of a method for the determination of low contents of fibres in bulk material - Final Report - European Community Contract No. MAT1-CT93-0003", Arbejdsmiljoinstituttet, Final Report, November 1997, pp. 1 – 74.

[69] **[RJLG footnote]** A. Wylie, K. F. Bailey, J. Kelse, R. Lee (1993). "The Importance of Width in Fiber Carcinogenicity and Its Implications for Public Policy", AIHA Journal, 54, p. 239-252.

[70] **[EPA footnote]** Both Addison (Addison J, Davies LST. 1990. Analysis of amphibole asbestos in chrysotile and other minerals. Ann Occ Hyg, Apr;34(2):159-75) and members of the U.S. EPA 2003 Peer Consultation panel raised concerns about interpretation of the Davis study (Davis JM, McIntosh C, Miller BG, Niven K. 1991. Variations in the carcinogenicity of tremolite dust samples of differing morphology. Ann NY Acad Sci, Dec; 643:473-90), which attempted to compare the toxicity of asbestos fibers and cleavage fragments. These concerns reflected the lack of peer review, use of intra peritoneal injection instead of inhalation exposure, significance of mesotheliomas caused by structures reported as cleavage fragments, purity of the cleavage fragment samples and issues related to fiber dimensions.

RJLG Response: The Yamate method[31] discriminates between asbestos and nonasbestos amphibole as does the NIOSH 7402 method. Even the EPA AHERA method specifies the counting and reporting of the asbestos varieties of the amphibole minerals. Lacking in those methods are detailed specifications for identifying nonasbestos amphibole particles. However, such guidance is provided by Crane[3] (OSHA ID-191) and the EPA PLM method[56] for the analysis of bulk materials. Given the recent confusion over identification of cleavage fragments, it would be useful to standardize procedures and train microscopists regarding appropriate methods for making the distinction between asbestos and nonasbestos particles.

"In terms of epidemiological data and health outcomes, the cleavage fragment argument is without merit. For the purposes of public health assessment and protection, EPA makes no distinction between fibers and cleavage fragments of comparable chemical composition, size, and shape."

"There are no recognized analytical protocols, including those used by EPA, NIOSH, MSHA, ASTM, and ISO, which include criteria to differentiate between cleavage fragments and crystalline fibers."

RJLG Response: As pointed out above, there are in fact protocols that include criteria to differentiate between cleavage fragments and fibers. However, even though the methods do not provide specific criteria for the classification of cleavage fragments, they all specify the counting and reporting of asbestos structures or asbestos varieties of specific minerals. It is the responsibility of the laboratory and accrediting agencies to ensure that the methods are being appropriately implemented. While the methods generally do not specify the procedures for the identification of amphiboles or serpentines, they do specify the minerals to be counted. Thus Lab/Cor's inclusion of particles identified as hornblende in reporting the asbestos concentration is inconsistent with the ISO 10312 method or any other analytical method.

The contention that cleavage fragments cannot be differentiated from asbestiform particles was evaluated for the El Dorado Hills soil. This was done by comparing the SEM and TEM images of the asbestiform fibers meeting two or more of the characteristics described in the NIST SRM 1867a with the morphology of amphibole particles found in the soil from the test sites. Images and SAED patterns of more than one hundred particles from El Dorado Hills soil are compared with the images of asbestiform particles from Harvard Way, San Andreas, and Jamestown, California, asbestos samples all representing naturally occurring asbestos. These data illustrate that, in this case, the distinction can be made effectively by using the SAED pattern, the

TEM image, and the SEM image. Thus, while the argument of indistinguishability may have merit in some instances, there is no evidence that it has any merit at El Dorado Hills. The images are shown in Attachment A-4a.

"All these methods require that structures which meet their definition of the specific counting rules for an asbestos fiber be counted. The requirements are based on the fact that, in the words of an expert from the United States Geological Survey, "At a microscopic level, distinguishing between these forms on single [asbestos] particles, can be extremely difficult to impossible."[71] *As noted above, R.J. Lee made a very similar claim with regard to cleavage fragments as the expert witness for W.R. Grace in the Libby, Montana, Superfund cost recovery litigation.* ***The EPA analytical experts who reviewed the R.J. Lee Group's testing methodology related to the Libby site found that the R.J. Lee laboratory could not demonstrate any reliable criteria with which to distinguish, at the microscopic level, asbestos cleavage fragments from asbestos fibers of the same size, shape, and composition. The Ninth Circuit Court of Appeals recognized the competing scientific arguments but found that EPA's position was consistent with the record of evidence and accepted scientific principles.***[72]***"***

RJLG Response: RJLG uses the same procedures that OSHA and MSHA laboratories use to distinguish between asbestos and nonasbestos minerals. EPA's Yamate method[31] notes that asbestos amphiboles produce SAED patterns with 0.53 nm d-spacing whereas nonasbestos amphiboles generally do not and states that morphology should be the final arbiter. Moreover, RJLG reports both asbestiform and nonasbestiform amphiboles in the counted structures specifically so that risk experts can use the definition they deem appropriate to estimate risk. This procedure has been used by RJLG as a participant in other EPA studies.[73]

It is RJLG's understanding that the scientific arguments were not addressed by the Ninth Circuit Court of Appeals. RJLG is unaware of an EPA expert report or testimony in the Libby matter that suggested RJLG's testing methodology was flawed.

3.5 R.J. Lee Finding #5:"Applying the Latest Science and Definitional Techniques, the El Dorado Hills Study Shows no Significant Exposure to the Type of Amphibole Asbestos Fiber Connected To Health Risk."

"The R. J. Lee Report claims that the latest science for measuring the risk posed by asbestos is the Berman-Crump Asbestos Risk Assessment Protocol ("Berman-Crump") which proposes that

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[71] **[EPA footnote]** G.P. Meeker, USGS, (2002). Review of Expert Report of R.J. Lee.
[72] **[EPA footnote]** U.S. v. W.R. Grace, 429 F.3d at 1245.
[73] **[RJLG footnote]** P. Lioy (2001). Quality Assurance Project Plan: Assessment of Population Exposure and Risks to Emissions of Protocol structures and Other Biologically Relevant Structures from the Southdown Quarry".

amphibole asbestos fibers which are more than 10 microns long and less than 0.5 microns wide (protocol fibers) are the most toxic. Of the 2,386 fibers which the R. J. Lee Report states the EPA laboratory identified, the R.J. Lee Report concludes that only 7 fibers meet the "Berman-Crump" definition. Therefore, the R.J. Lee Group maintains that EPA has overstated the risk from exposure to asbestos fibers in El Dorado Hills."

EPA Response:

"The "Berman-Crump" protocol that the R.J. Lee Report references is in fact a draft EPA method. EPA had the method reviewed by a peer consultation panel in 2003. The panel made a number of important recommendations that must be addressed before the method can be used for EPA risk assessments. A number of important revisions have been made to the draft method since 2003, but at this time the method has not been independently peer reviewed. It will not be adopted by EPA as a risk assessment tool unless and until it passes rigorous internal and external peer review."

"The expert peer panel has recommended that the fiber size for the draft EPA risk assessment method be adjusted to include fibers greater than 5 microns in length and up to 1.5 microns in width.[74] The change is designed to account for lung deposition of fibers that results when fibers are inhaled through the mouth, and not filtered by the nasal passages. The broadening of the fiber definition to include inhalation by "mouth breathers" is especially relevant to the El Dorado Hills data. Our investigation measured personal asbestos exposures of individuals participating in sports activities, where physical exertion would likely increase breathing through the mouth. ***The PCME fibers counted in the EPA air samples are actually consistent with the latest science of EPA, as reflected in the recommendations of the peer consultation panel. In addition, the EPA peer consultation expert panel recommended that cleavage fragments be treated as any other asbestos fiber of the same morphology and chemical composition.[75]"***

RJLG Response: EPA Region 9 has made the transition from arguing that cleavage fragments of the same dimensions as asbestos fibers should be treated as equally potent as asbestos, absent definitive evidence to support this view, to defining cleavage fragments as asbestos, all this without the benefit of medical data, peer review, or regulatory authority. It is our understanding that Dr. Wayne Berman[50] will be comprehensively addressing this aspect of the EPA Response.

"EPA Region 9 focused on obtaining an accurate count of PCME structures, consistent with our risk assessment protocols and those of Cal/EPA and other health agencies. The counting rules which EPA set for the laboratory were designed to stop counting when a statistically-significant number of PCME fibers were detected. ***By concentrating on PCME structures, other fiber size classifications may not have been counted to statistical significance. This may have resulted in under counts of other fiber sizes (e.g. the "Berman Crump" protocol fibers***

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[74] **[EPA footnote]** USEPA (U.S. Environmental Protection Agency) (2003). Report on the Peer Consultation Workshop to Discuss a Proposed Protocol to Assess Asbestos-Related Risk, Final Report. Office of Solid Waste and Emergency Response, Washington D.C. Page 5-5.
[75] **[EPA footnote]** Ibid, page 5-1.

referred to in the R. J. Lee Report). *EPA Region 9's study counted PCME structures so that the data could be directly compared to human health epidemiological studies."*

RJLG Response: Structures shorter than 5 μm in length accounted for nearly 60% of all reported structures in the Lab/Cor data, thus reducing the reliability of the estimates of particles now generally accepted as the most potent. Indirectly, however, EPA Region 9 makes a valid point – that other fiber size classifications may not have been counted to appropriate statistical significance. All asbestos analyses represent an index of the total exposure. The goal of any asbestos analysis is to get the most reliable count of the most potent component of the exposure possible. EPA's decision to count all particles with a ≥3:1 aspect ratio resulted in spending valuable resources identifying particles that did not have parallel sides or other characteristics of asbestos particles while reducing the reliability of the data obtained on any actual asbestos present in the aerosol and defeated the purpose of the study.

"These epidemiological studies form the basis for risk assessment models currently used by EPA, Cal/EPA and other federal agencies and international organizations."

4.0 R. J. Lee Report Peer Reviews

"The R. J. Lee Report was reviewed by three individuals, although research of one of the individuals was extensively quoted in the report and therefore the independence of the reviewer is debatable."

"The three reviewers generally agree with the conclusions of the R. J. Lee Report regarding aluminum content, fiber chemistry, cleavage fragments, and extinction angles."

RJLG Response Mr. John Addison,[18] a noted mineralogist, has recently reviewed the RJ Lee Group report and is in general agreement with RJLG. The NIST SRM 1867a cited by EPA Region 9 describes the properties of asbestos in a manner consistent with the EPA QAPP, and inconsistent with the EPA Region 9 response. Importantly, the language of the NIST Certificate specifically differentiates between the extinction angles certified in the standard and the extinction angles of the asbestos fibers in the standard noting the unique properties of asbestos may produce anomalous or parallel extinction.

"Both the R. J. Lee Report and one of the reviewers support use of the original "Berman-Crump" protocol and calculate a "Berman-Crump" fiber air concentration of 0.0002 fibers/cubic centimeter, using the EPA fibers which they assert meet the "Berman-Crump" definition. The peer reviewer then compares that concentration with an ambient concentration of 0.0008 fibers/milliliter measured in New York City, and states that the "Berman-Crump" value in El Dorado Hills is extremely low. This comparison is flawed for at least two reasons. Significantly, the New York City numbers are based on fibers counted against a totally different size classification (essentially comparing apples to oranges), but the reviewer also fails to recognize

that a concentration of 0.0002 f/cc translates in the protocol to an increased cancer risk of 1 in 1,000 exposed individuals. This number is disturbingly high and is outside the acceptable cancer risk ranges of EPA, Cal/EPA, and most other state and federal health agencies."

5.0 Conclusions

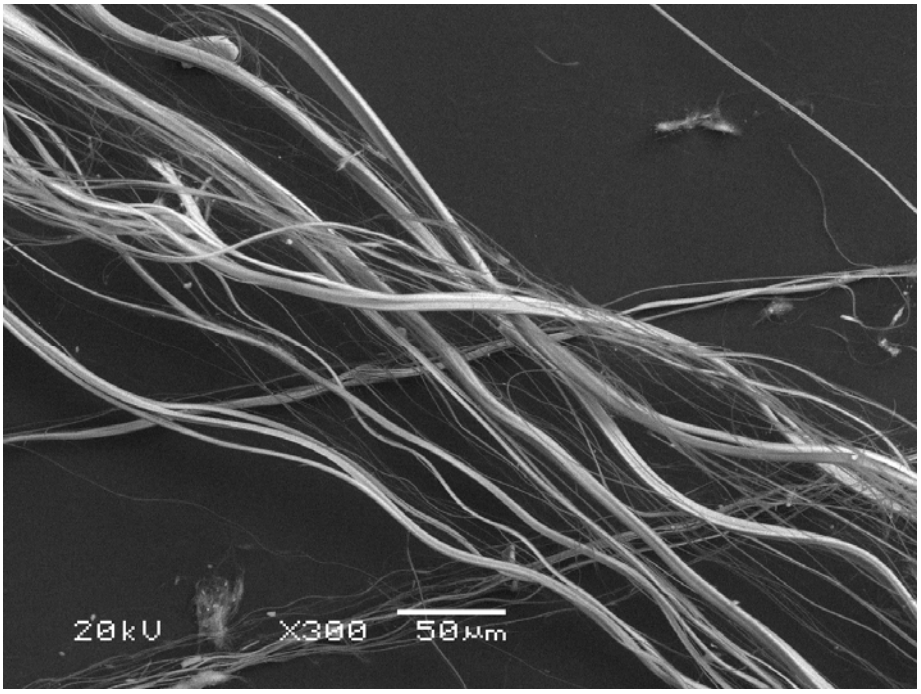
EPA Region 9 has carefully reviewed the R. J. Lee Report and believes that it makes largely unsupported and incorrect conclusions about the EPA Region 9 El Dorado Hills Naturally Occurring Asbestos Exposure Assessment. EPA Region 9 has asked the United States Geological Survey (USGS) to conduct an independent study of the El Dorado County area to address several mineralogical questions raised by the R. J. Lee Report. The USGS study will use sophisticated analytical techniques (such as electron probe micro analysis) to more completely characterize the naturally occurring asbestos in terms of mineral identification and particle morphology.

All of the EPA Region 9 work in El Dorado Hills was, and continues to be, consistent with the EPA's standard operating and quality control procedures for asbestos work throughout the country.

6.0 RJLG Attachments

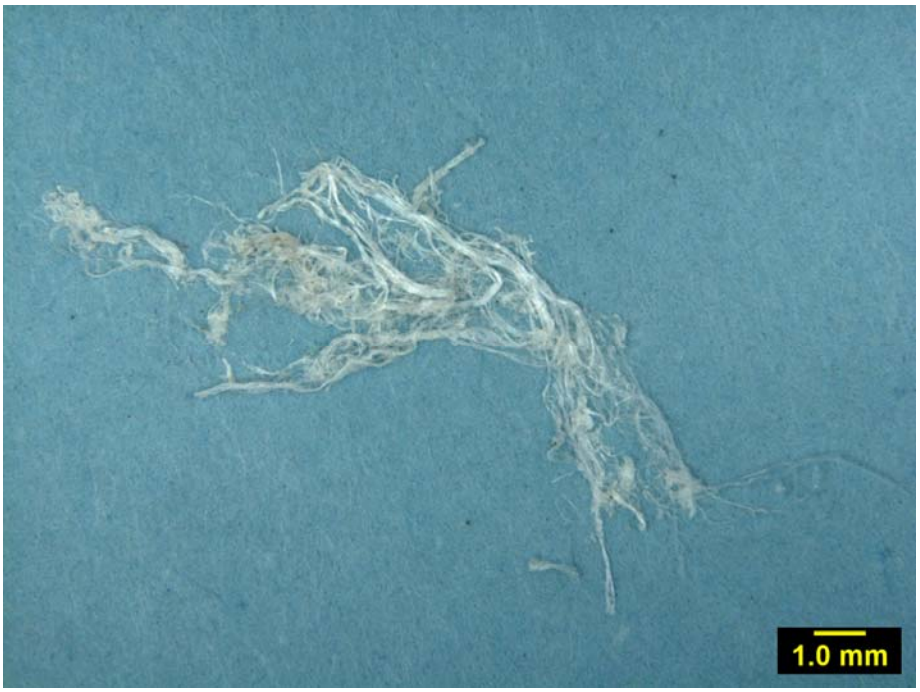
Attachment A-1

Optical Image of Chrysotile Grade 3 (textile grade).

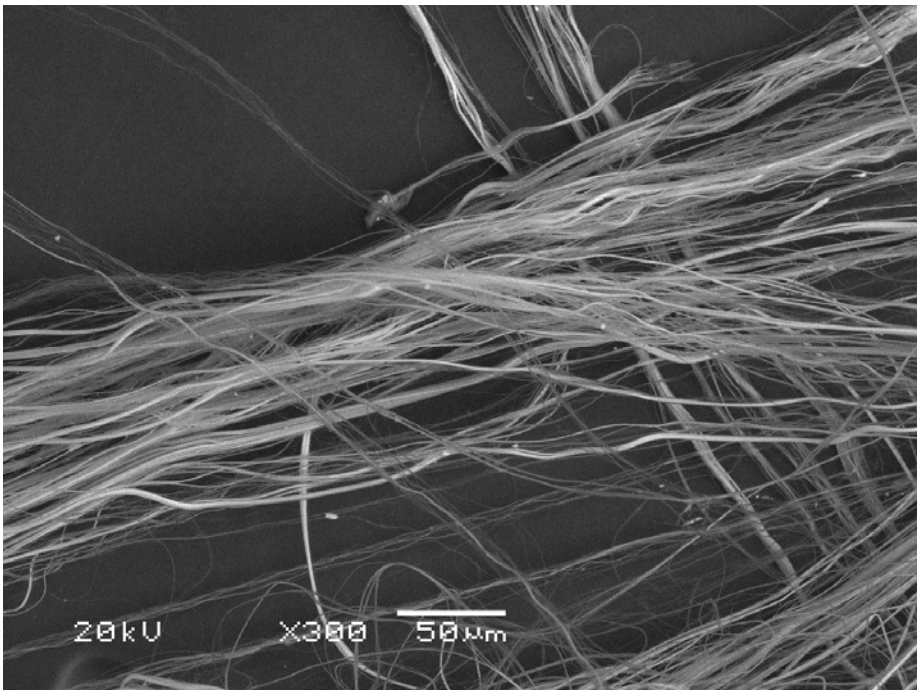


SEM Image of Chrysotile Grade 3 (textile grade).

Attachment A-1 (continued)



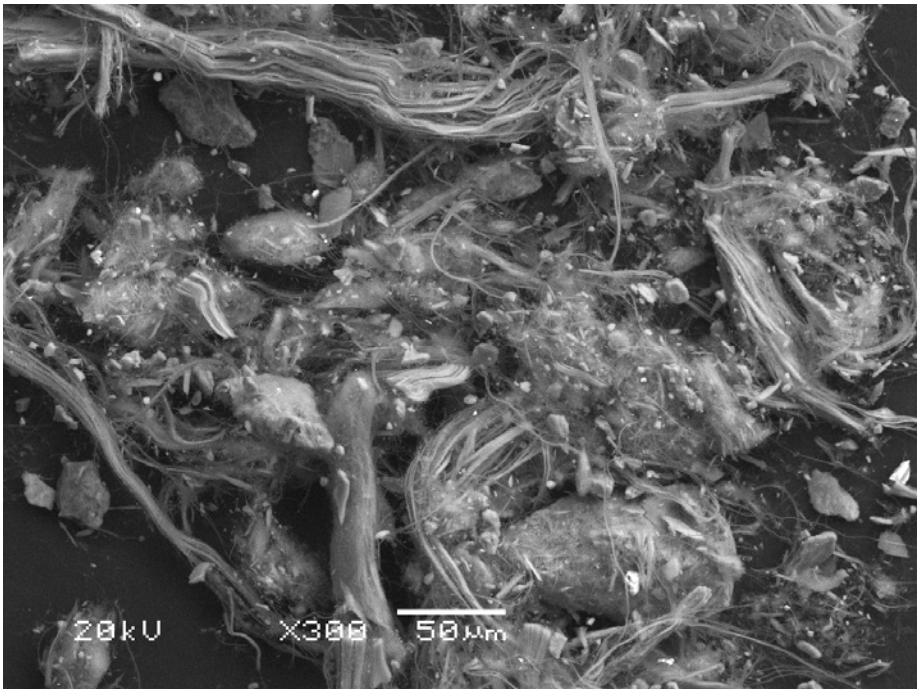
Optical Image of Chrysotile Grade 4 (insulation/cement pipe grade).



SEM Image of Chrysotile Grade 4 (insulation/cement pipe grade).

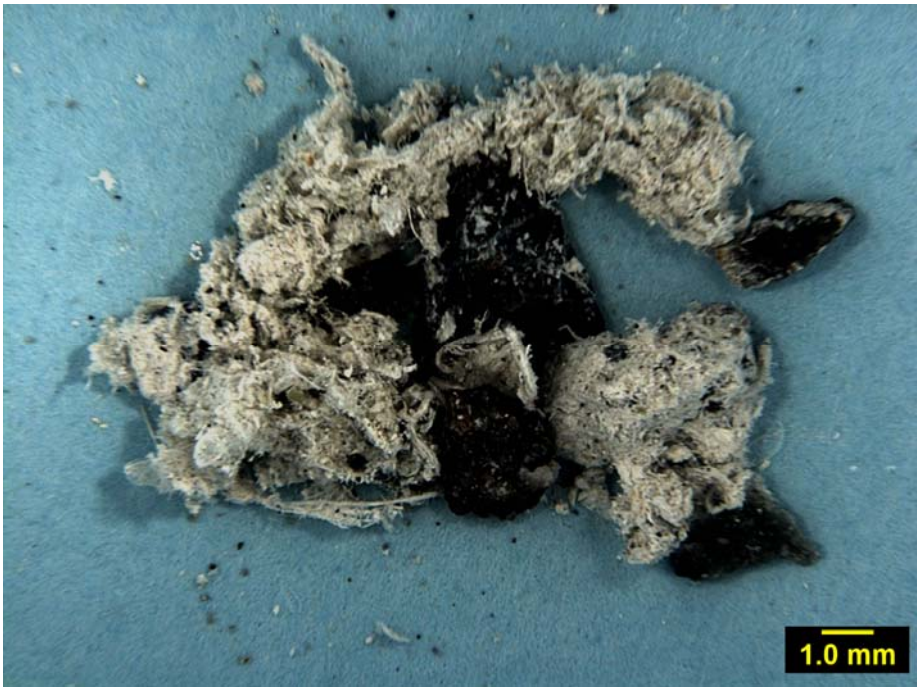
Attachment A-1 (continued)

Optical Image of Chrysotile Grade 7 (friction parts grade).

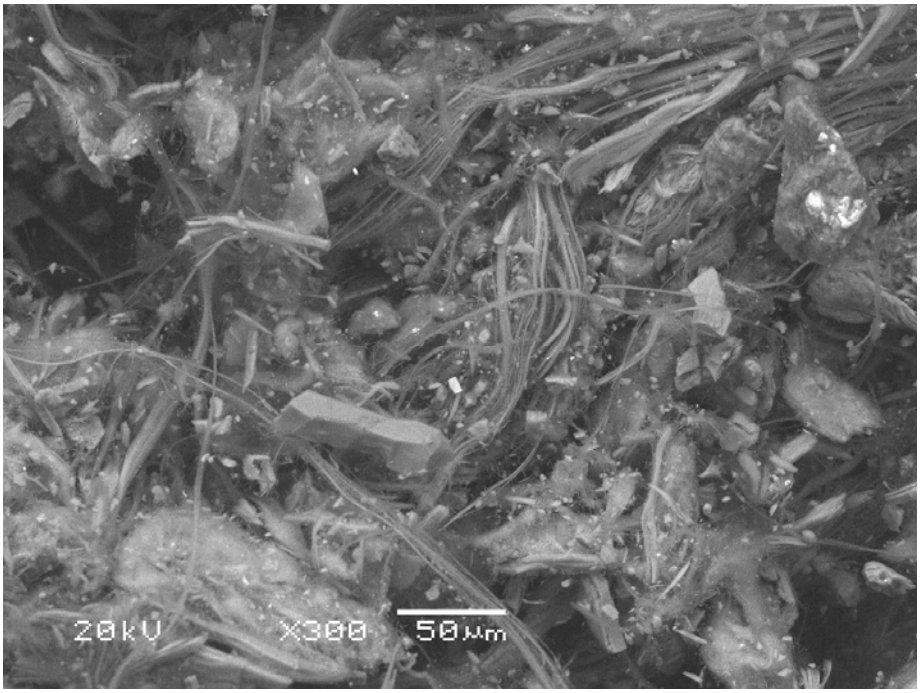


SEM Image of Chrysotile Grade 7 (friction parts grade).

Attachment A-1 (continued)

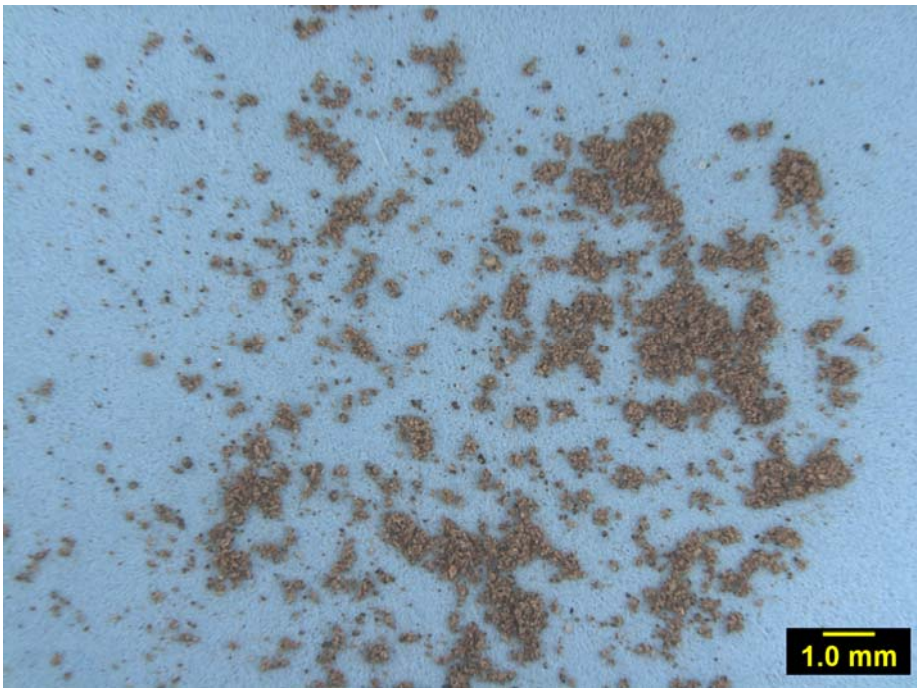


Optical Image of Chrysotile Ore (Quebec chrysotile miner exposure).

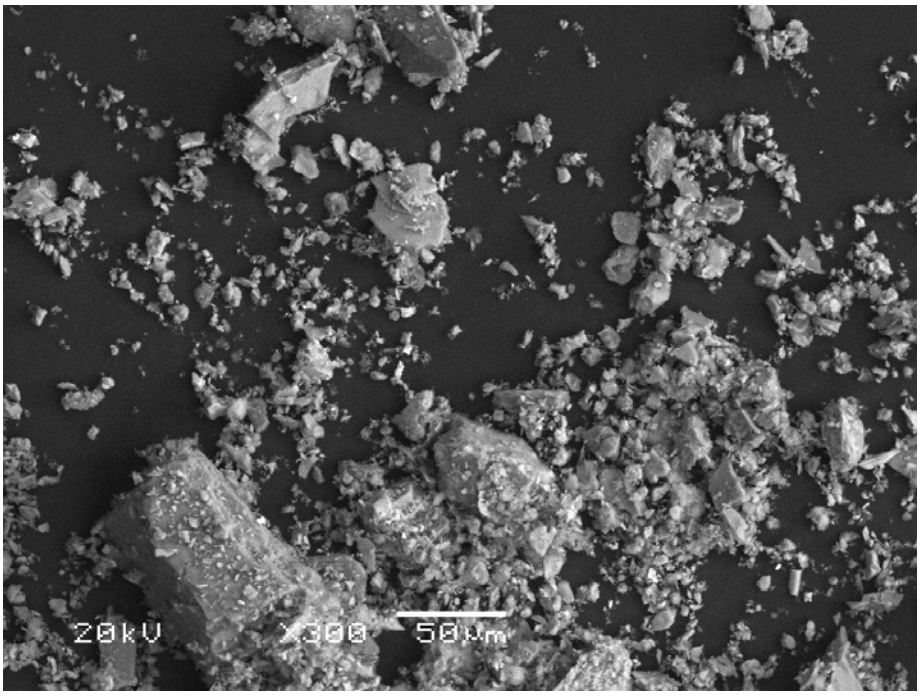


SEM Image of Chrysotile Ore (Quebec chrysotile miner exposure).

Attachment A-1 (continued)



Optical Image of Eldorado Hills EPA Soil Sample.



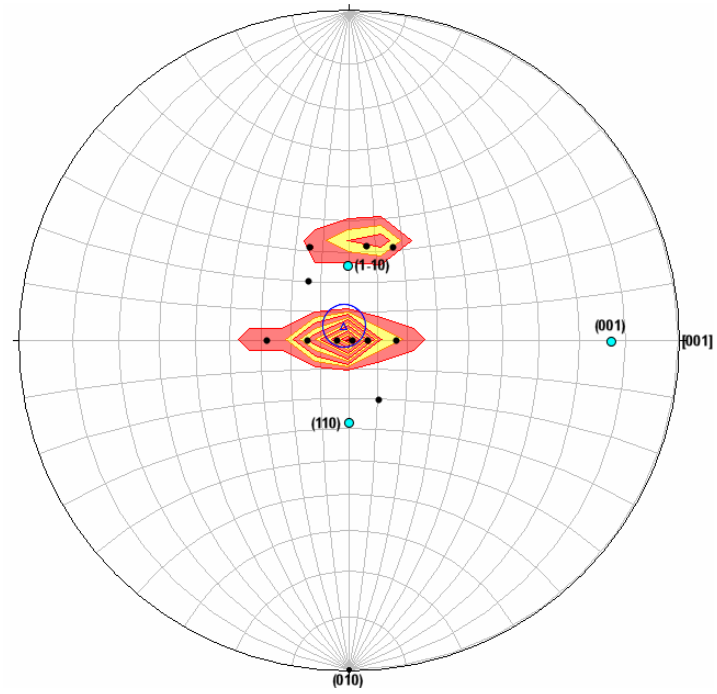
SEM Image of Eldorado Hills EPA Soil Sample.

Attachment A-2

Stereographic projections may be used to evaluate crystallographic orientations of electron diffraction patterns, and through them, the orientations of individual particles or crystals. Each pattern represents specific crystal planes and can be represented as a point on the stereographic projection. Amphibole particles have three major crystallographic directions called the (100), (010) and (001) directions, and have a perfect cleavage face corresponding to (110). The long axis of an amphibole particle is the (001) crystal axis. Asbestiform fibers tend to lie on the (100) face and cleavage fragments tend to lie on the (110) face. Plotted in the stereographic projections shown are the points representing the patterns collected from tremolite asbestos from Jamestown, California and the patterns reported by Lab/Cor for the El Dorado particles. The difference in particle orientation is obvious. The Jamestown fibers cluster about the (100) direction whereas the Lab/Cor El Dorado particles, while clustering about the (110) direction, have a large amount of scatter. Only about 20% of the particles lie on the (100) face which is as to be expected for a nonasbestos population.

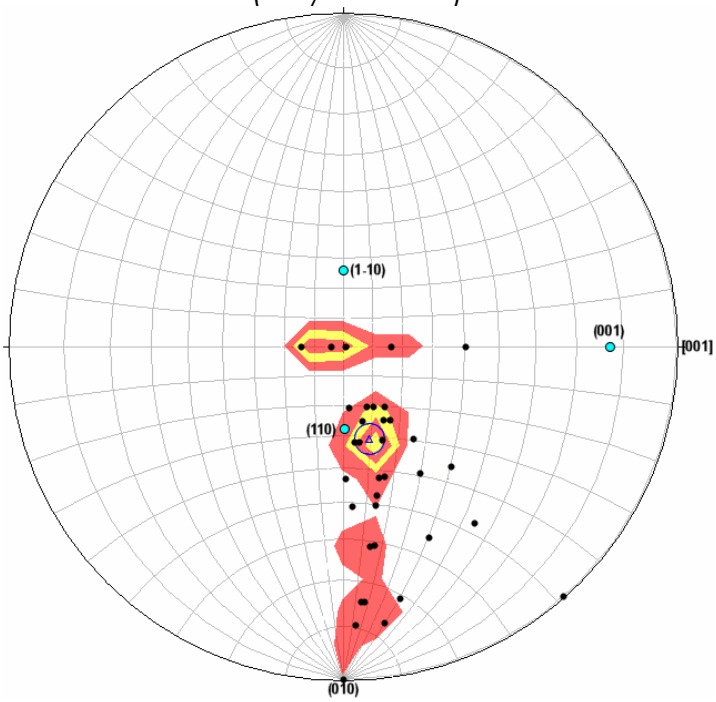
Stereographic projections of...

33 Jamestown Zone Axes viewed down (100)



Mean vector lies along (100) pole
Contour interval: 4%

132 El Dorado Zone Axes viewed down (100)
(Lab/Cor Data)

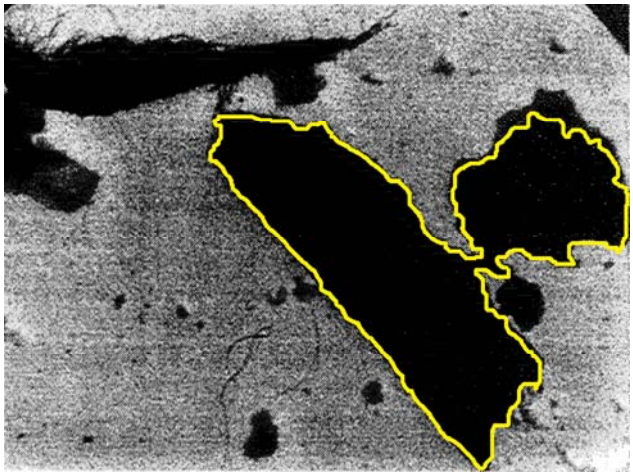


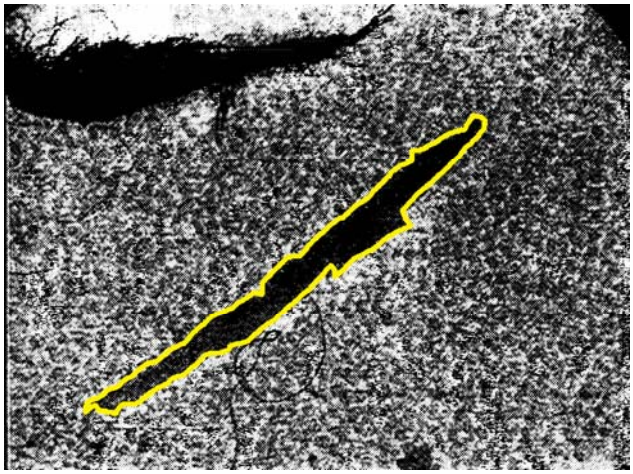
Mean vector lies along (110) pole
Contour interval: 4%

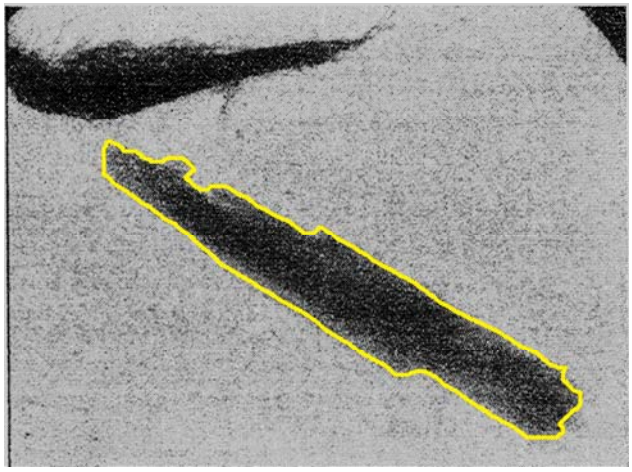
StereoWin 1.2 – R.W. Allmendinger (2003)

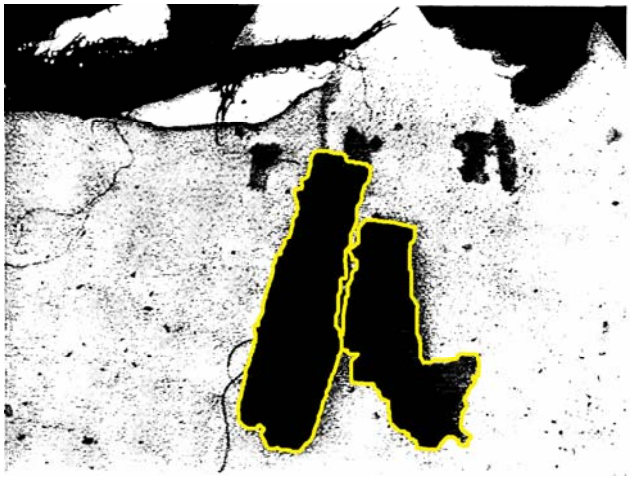
Attachment A-3

A major quality issue leading to the exaggerated asbestos counts in the EPA El Dorado Hills Study was the failure to follow the counting rules specified in the ISO 10312 TEM asbestos analysis method. The ISO 10312 method specifies that particles having parallel or substantially parallel sides are to be counted. Shown below are representative photographs provided by Lab/Cor, and as seen, very few have parallel or substantially parallel sides. The edges of the particles are highlighted to aid the viewer. Copies of all photographs Lab/Cor provided of the particles they analyzed are provided in a separate document (Attachment A-3a).





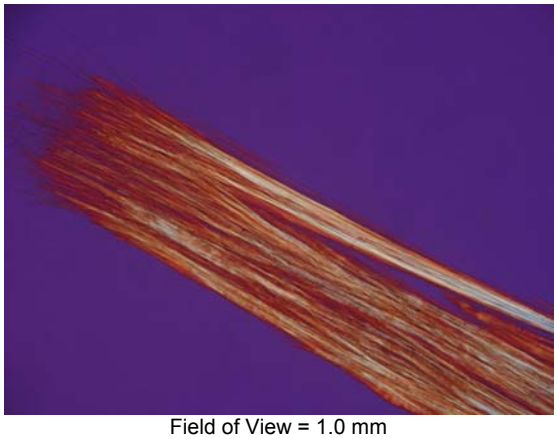




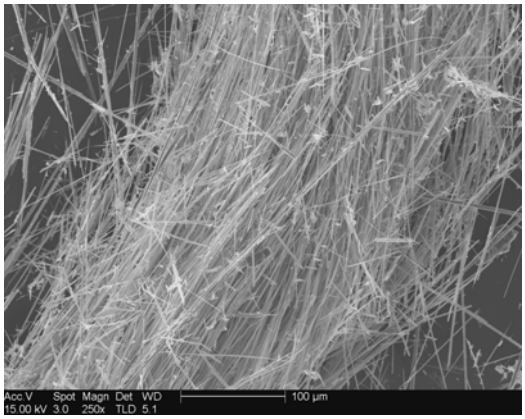
Attachment A-4

Region 9 suggested that it might be impossible to differentiate nonasbestos amphiboles from asbestiform amphiboles at El Dorado. To examine this question RJLG collected asbestiform samples from Harvard Way near the EPA test site. In order to illustrate the difference between asbestiform fibers and the nonasbestos particles in the El Dorado Hills soils, polarized light micrographs and SEM photographs of asbestiform particles from Jamestown, California, Harvard Way near the EPA test site in the El Dorado Hills Study, and soil samples from the El Dorado Hills Study were examined. The amphibole particles in the El Dorado Hills soils sample are highlighted.

Jamestown Tremolite

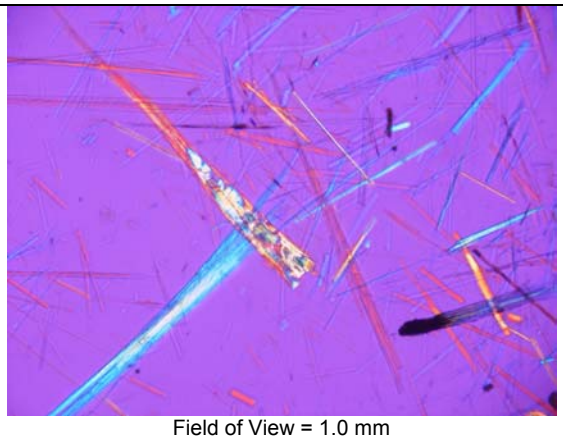


Field of View = 1.0 mm

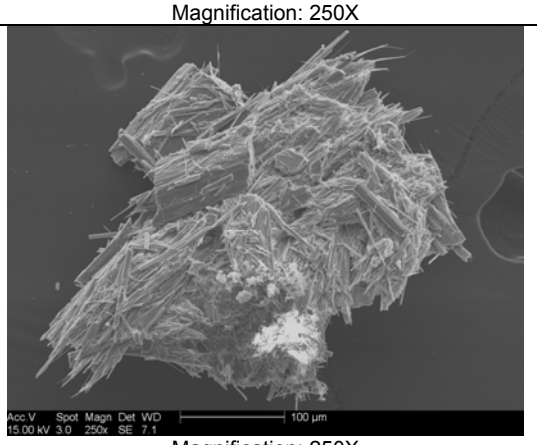


Magnification: 250X

Harvard Way

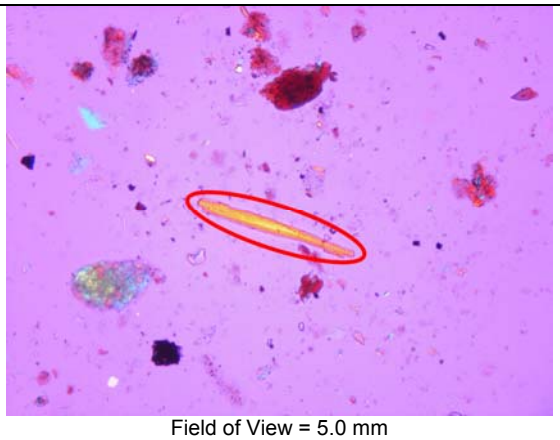


Field of View = 1.0 mm

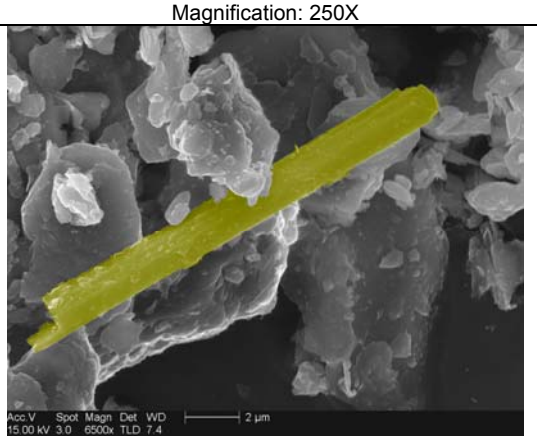


Magnification: 250X

El Dorado Soil



Field of View = 5.0 mm



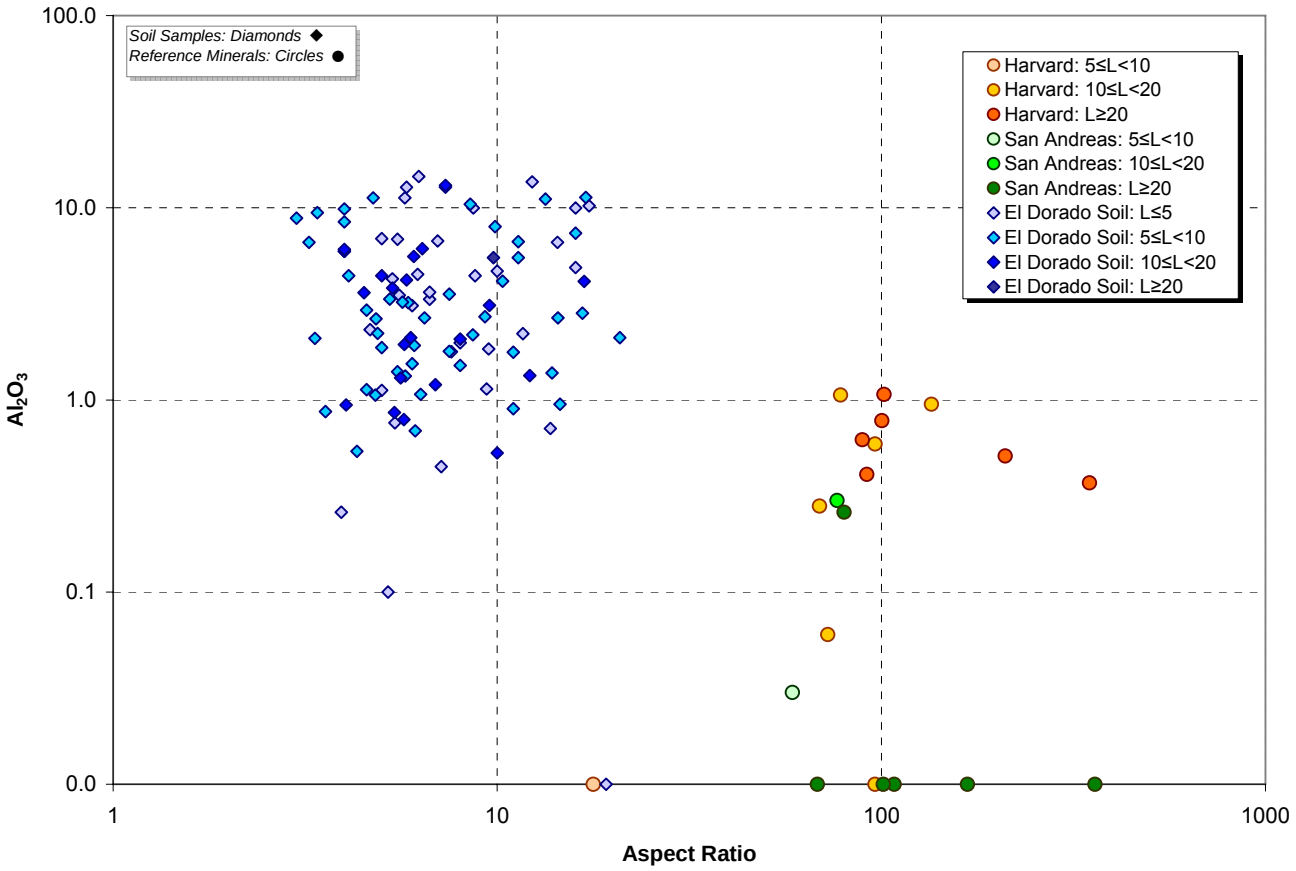
Magnification: 15000X

Attachment A-4 (continued)

Additional images documented by RJLG are included in Attachment A-4a (a separate document) which includes RJLG images of particles imaged by TEM and FESEM together with corresponding EDS spectra and SAED patterns. These data clearly demonstrate that elongated particles observed in the El Dorado Hills soil samples do not have the same characteristics as those of asbestiform amphiboles (e.g., Harvard Way, Jamestown).

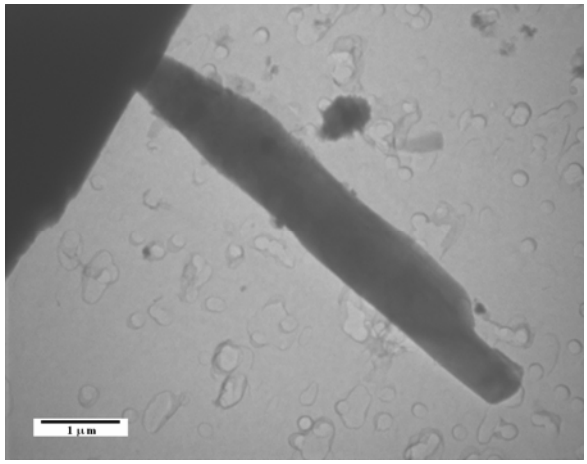
Attachment A-5

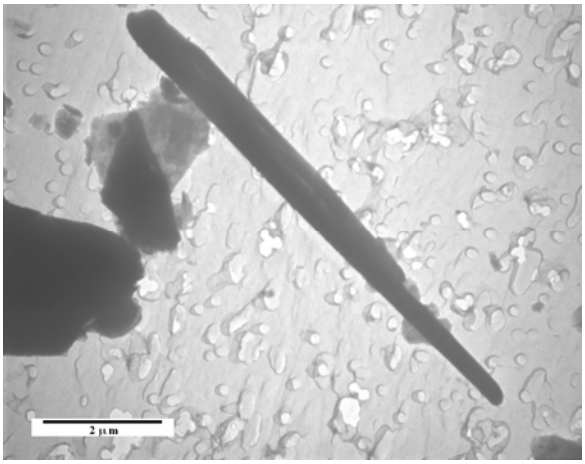
Region 9 and Mr. Meeker disputed RJLG's statement that the El Dorado Hills particles contained too much aluminum to be asbestiform. To evaluate this, asbestiform tremolite from Harvard Way and San Andreas, California were analyzed. The graph shown compares the aluminum content to the aspect ratio for particles from the El Dorado Hills soil with particles from San Andreas and Harvard Way. The asbestiform particles have the high aspect ratios and low aluminum content characteristic of asbestiform actinolite and tremolite whereas the soil particles have much lower aspect ratios and higher aluminum content.

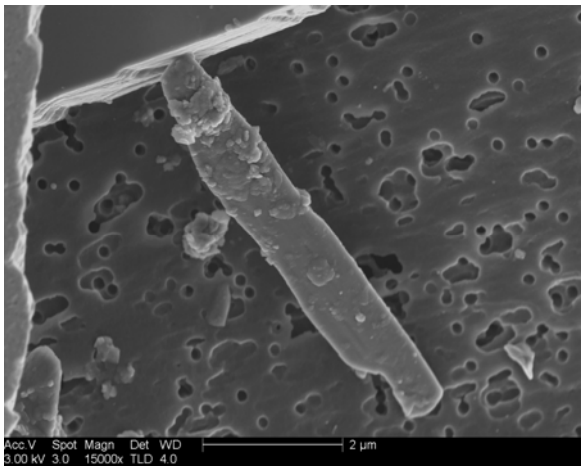


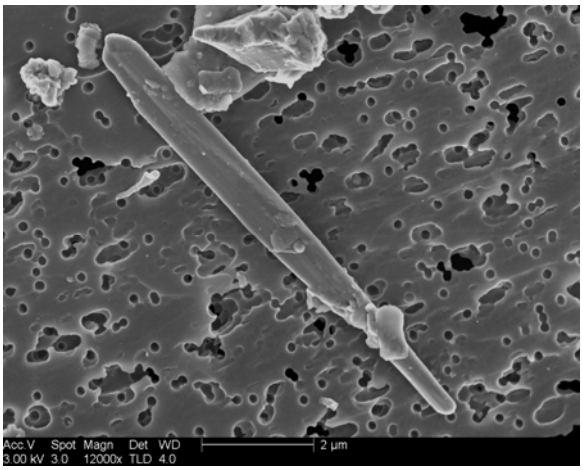
Attachment A-6

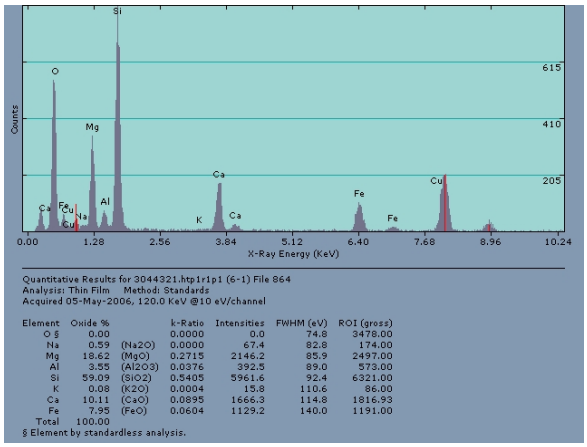
Region 9 suggested that the aluminum content of the El Dorado Hills particles could have originated from contamination by clay particles that contain aluminum. To examine this RJLG examined soil particles in the SEM and TEM. As seen below (Sample 3044321, EPA sample no. CPS-S05-100804-FG2), the amphibole particles had generally clean surfaces, and in cases where there were surface coatings, areas free of the coating could be located which still had high aluminum concentrations.

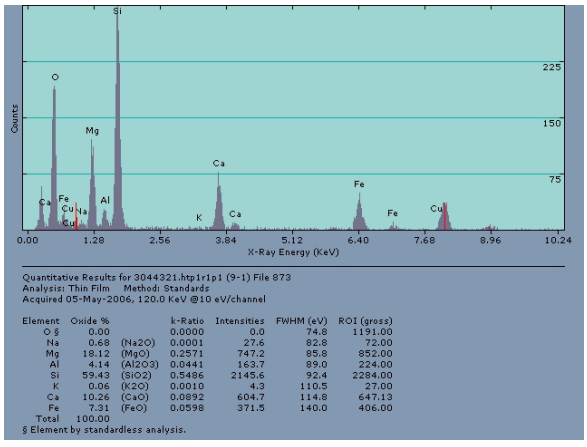






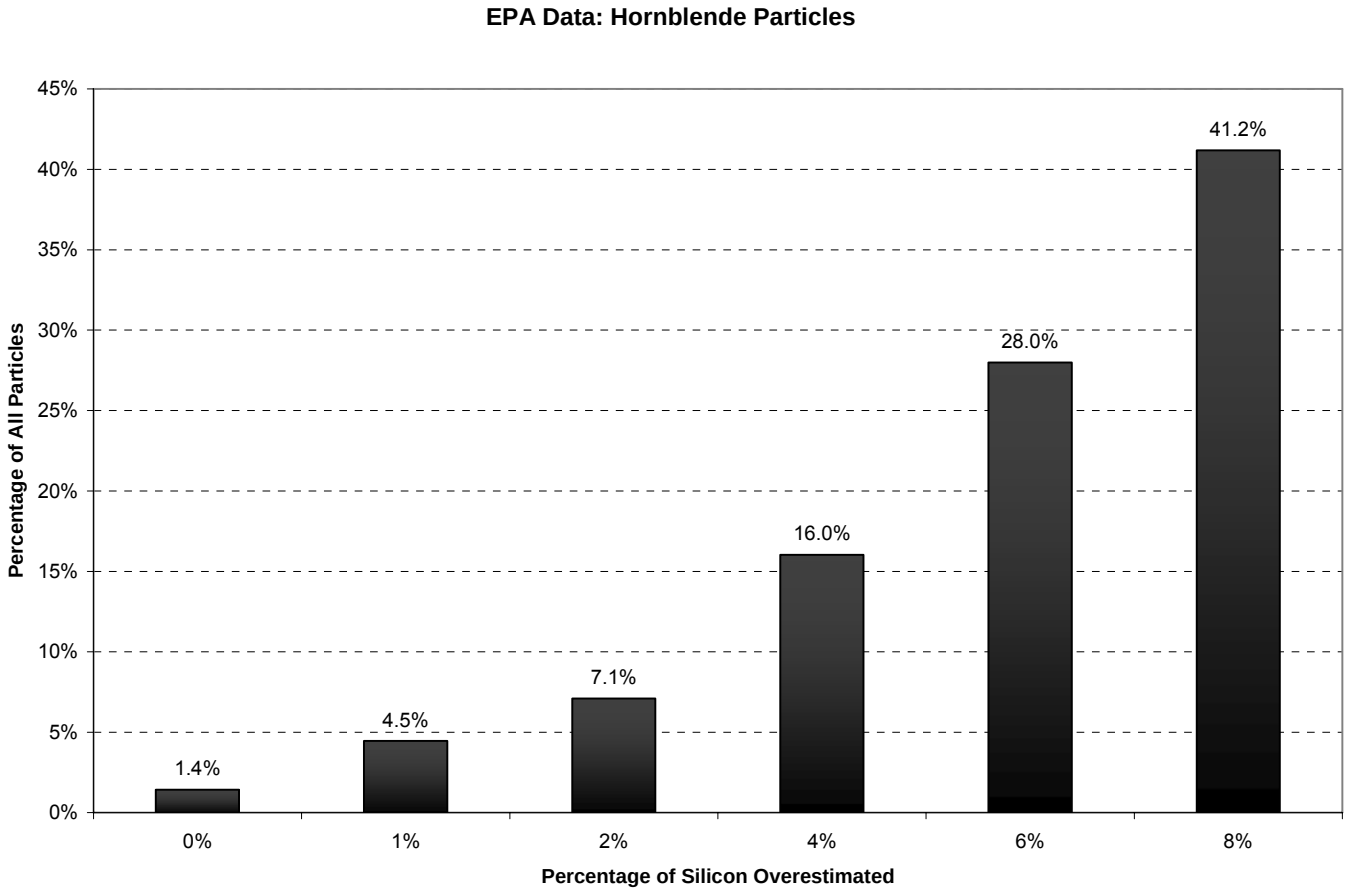






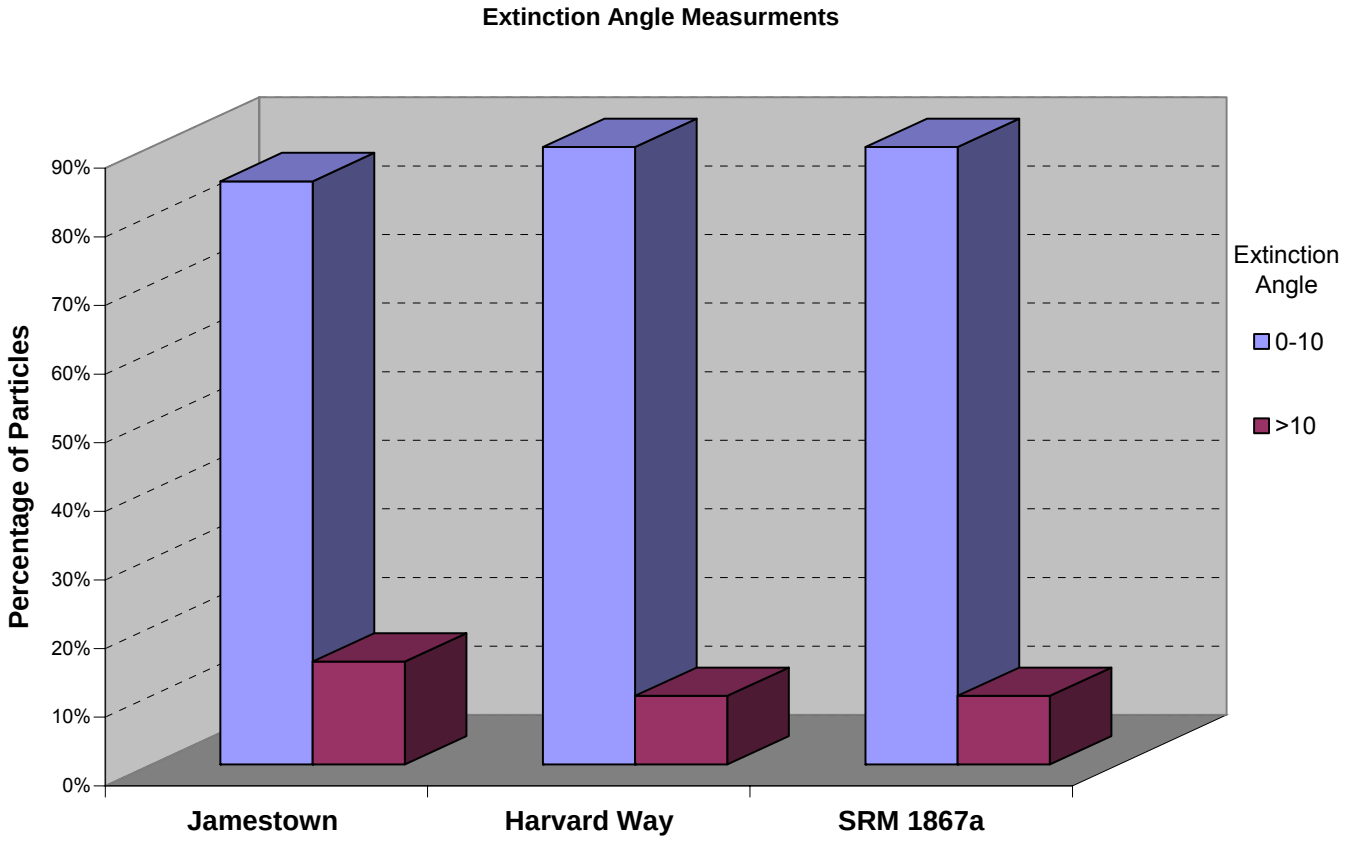
Attachment A-7

The elemental analysis performed by Lab/Cor to determine the IMA mineral classification used normalized energy dispersive spectroscopy (EDS) data. Normalization of elemental concentrations performed as part of an EDS analysis is known to result in an over-estimation of the silicon concentration in silicate minerals. For example, if an EDS spectrum is acquired and the sum of all peaks is 89, the resulting data are "normalized" to sum to 100. In this example, if a silicon peak was measured at 50 wt. %, the normalized data for silicon will be reported as 56 wt. %. Such a difference in the silicon concentration has a dramatic effect when classifying amphibole mineral species using IMA methodology. As shown below, if Lab/Cor overestimated the silicon concentration by 6% then 28% of the amphibole particles would be misidentified. Thus there is a very high degree of uncertainty in the mineral assignments made by Lab/Cor.



Attachment A-8

EPA Region 9 and Mr. Meeker suggest that naturally occurring asbestos may not have parallel extinction. RJLG evaluated the extinction angles of asbestiform fibers from Jamestown, California, Harvard Way near the test site, and the NIST SRM 1867a standard. In all cases the vast majority of asbestiform particles had parallel extinction as illustrated below. Attachment A-8a (a separate document) shows photographs of particles from each sample and gives their related extinction angles.



Attachment A-9

It is generally recognized that an important parameter of asbestos fibers is the fine diameter of the particles. The graph shown compares the width of particles found by Lab/Cor with the amphibole particles used by Davis[26] in animal studies. The finest width distribution is that of the Jamestown asbestos which was found to be highly toxic. The Shinness particles are coarser but still finer than the El Dorado Hills particles. The Shinness particles were found to be nontoxic by Davis, suggesting that the El Dorado Hills particles would be nontoxic.